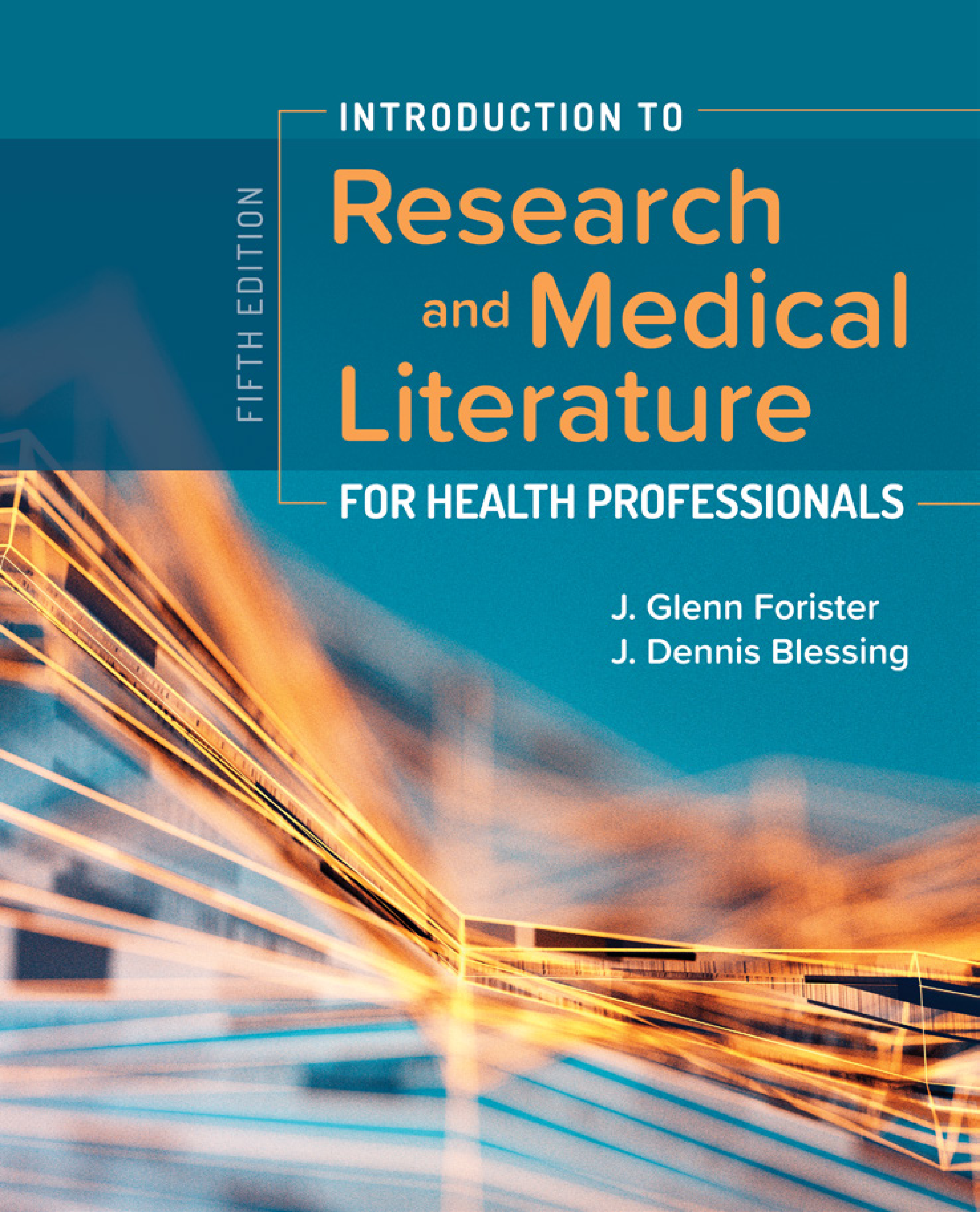
INTRODUCTION TO

Research and Medical Literature

FOR HEALTH PROFESSIONALS

FIFTH EDITION

J. Glenn Forister
J. Dennis Blessing



FIFTH EDITION

INTRODUCTION TO Research and Medical Literature FOR HEALTH PROFESSIONALS

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Dedication

The fifth edition of this book is dedicated to all of the contributors who have put forth their effort to improve the research capabilities of healthcare professionals, present and future. We further dedicate this book to our friends and colleagues at Jones & Bartlett Learning. They have worked behind the scenes for many years to make us look good.

Ultimately, the contributors and publishers want this to be a successful book that helps every reader in their understanding of research and what it means to the people who benefit from our healthcare efforts.

JGF
JDB

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Preface

The editors of and contributors to this book are dedicated teachers, librarians, researchers, administrators, and practitioners in healthcare professions. They have worked tirelessly to make this book readable, understandable, and useful for students and practitioners in healthcare professions. Our intent is to provide a tool that can be the first step in understanding research and, perhaps, the first step in a research career. We hope this book places that first step on a sound footing without intimidation.

Research articles, news flashes, and advertisements bombard us daily. To make sense of it all, we must be able to interpret and apply the information in our patients' best interests. This skill is a critical requirement of clinical practice in today's world, and it requires an understanding of the research process.

▸ Conceptual Approach

We have tried to present our material in stepwise order, beginning with the protection of human subjects and the formation of a research question. Next, we consider different types of literature review and research methodologies. The analysis, results, and discussion sections follow. We also consider the writing and publication process. Finally, a chapter on the interpretation of the literature covers the skills a health professional must develop to be a consumer of the literature.

Ultimately, understanding the research process and interpretation of the research literature are inextricable—this book addresses both at the basic level. Our contributors represent a wide range of healthcare and education professionals with expertise in different aspects of research; however, each contributor has written with the novice researcher or clinician in mind. Prior knowledge of research is not assumed.

▸ Organization and Features

Each chapter begins with a Chapter Overview designed to relate the essential information covered in the chapter. Basic Learning Objectives for the chapter are also provided. The important key terms for each chapter are highlighted in bold font, with definitions provided in the glossary. In most chapters, tables and figures are used to help summarize key information. The overall scheme allows the reader to move naturally through the research process, ending with concepts needed to interpret the research of others.

▸ New to This Edition

The changes in this edition are based on the feedback from readers of the previous edition. A newly revised chapter on the regulatory protection of human subjects provides readers with the historical context and rationale for regulations. The latest updates to the Common Rule have been added. We have updated and replaced prior chapters on literature review and references. New examples and updated references have been added throughout the remaining chapters. We have left the information most valued by readers. The language in this edition remains accessible while covering a variety of research methodologies, analysis, and writing tasks. We hope this edition is as useful to beginners as the prior editions have been.

Change Highlights

Ch 2 Reviewer-requested historical section on rationale for human subjects protection and IRB
Ch 2 Edits to reflect recent change in the Common Rule for exempt research
Newly written Ch 4 on review of the literature
Newly written Ch 15 on references

Updated examples and references throughout based on reviewer comments

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CHAPTER 1

Introduction

J. Glenn Forister, PhD, PA-C
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CHAPTER OVERVIEW

This chapter is designed to introduce health professionals and students to research. The chapter introduces readers to the basic definitions and sources of research. An outline is offered to aid in the development of a project or research agenda. Each small piece of research that can add to the body of medical knowledge results in improvement in the physical, mental, and social well-being of patients.

LEARNING OBJECTIVES

- Define *research*.
- Describe types of research.
- Describe and discuss the importance of research in the health professions.
- Begin to develop a scientific approach to study and practice.

▸ Introduction

The bottom line is that research determines almost everything that is practiced now and in the future. The word *research* frequently evokes an emotional reaction. Novice professionals may see research as a mysterious process that is difficult to understand and difficult to conduct. Students may not see the impact of a required research assignment on their future careers. Similarly, many clinicians may not connect research to their work. Research, however, provides an opportunity to explore, understand, and explain practice. By mastering research, healthcare professionals can enhance their clinical careers and improve patient outcomes.

Many clinical practices are becoming involved with clinical trials and quality improvement studies. This involvement makes understanding the scientific process and research a practice requirement. Beyond the possibility of being directly involved in research, every healthcare professional must understand how to interpret the literature. The decision to incorporate a new treatment modality depends on the ability to assess and understand the research that led to that modality. Additionally, healthcare professionals must be able to evaluate the literature regarding how it relates to patients and to evaluate the best treatment options.

Research and Students in Healthcare Professions

The word *research* sometimes conjures up the following images:

- Individuals hidden away in a lab doing something unrelated to everyday life
- Boring work forced on students
- The pursuit of information that has little application in the real world
- Not something a healthcare professional does in clinical practice

For many people, the research process is difficult to understand. Research often requires the use of formulas and language only other researchers comprehend. Research findings are often contradictory, leaving professionals wondering what to do with the information. Because it can be a confusing endeavor, clinicians and educators may not engage in research. However, research provides the basis for practice. It is the key to the present and future, regardless of one's profession, position, or function in health care. Healthcare practices are based on scientific research. The evidence produced drives artificial intelligence (AI) solutions in healthcare. In the future, healthcare professionals will find research-based, computer-guided recommendations to be part of their day-to-day job.

Practice can only advance by applying evidence of what works.

Research Equals Curiosity

Whether they realize it or not, everyone has researched in something. Seeking an answer to a question is a form of research. Even looking up a word in an online dictionary can be considered a form of research. Curiosity drives investigation. Indeed, much "research" is informal and without the systematic constraints required by formal research, but it occurs every day. Practitioners do research when they investigate the literature for solutions to patients' problems. Students do research as part of their education. Self-study and exam preparation are informal research processes.

Research occurs in the laboratory, classroom, office, and society at large. The results may be directly applicable to a problem or only a small piece of a broader solution. Learning how research works help relieve anxieties and increase the ability to appreciate and enjoy the process. Ultimately, the goal is to improve the lives of patients.

In some ways, research may be more important to the practitioner than to the student, but learning of these skills begins in training. Similarly, what interests a healthcare practitioner or student may be mundane but necessary to the profession or livelihood. For example, an occupational therapist may have little interest in the differences in practice census flows by disability type, but that information may have a significant impact on patient scheduling and clinical assignments. It may or may not require statistical analysis, but it requires the systematic gathering, analysis, and interpretation of information (data).

Another example of research application in practice is patient outcomes. What is the difference in practice outcomes between treatment regimen A and B? There may be a wealth of information in texts and the literature, but what happens in a particular practice setting? Personal research is needed to determine the answer, whether a formal or informal process is used. The values of informal versus formal research may be equal, but a formal investigation might lead to benefits beyond a single setting.

Research and the Students of Healthcare Professions

For a student, research is part of the task of discovery and learning. Research provides the information needed to build a fund of knowledge that guides what a student will do as a healthcare provider. Every student must become an informed consumer and learn to interpret the medical research and healthcare literature. At a minimum, learning how to interpret research findings is a necessary skill for a professional career. Useful interpretation skills allow healthcare practitioners to deliver an acceptable level of care.

Education in the healthcare professions should be consistent with adult learning theory. All healthcare practitioners should be lifelong learners; the healthcare professional that stops building his or her knowledge base and abilities will not be able to contribute to meaningful change. Experience is part of that knowledge base, but continuing to understand and interpret the literature is the foundation for maintaining, redefining, and increasing that base. Research is one tool that helps practitioners to "learn how to learn" and meet future healthcare challenges.

Research and Healthcare Professionals

The unknowns and seemingly complex methods of systematic research and its processes make some people uncomfortable. Data collection, statistical analysis, and interpretation can be daunting. Because the research world has its jargon, many healthcare professionals want to leave this activity to others. However, at a minimum, healthcare professionals must be able to interpret and apply research as steps in patient care. As healthcare professionals develop, they may find additional roles and responsibilities in the research arena.

Research Takes Many Forms

Research takes many different forms (**TABLE 1.1**). Research can be categorized in various ways, including pure research, experimental research,

TABLE 1.1 Types of Research

Type	Description	Example(s)
Pure	Abstract and general, concerned with generating new theory and gaining new knowledge for knowledge sake	Theory development
Experimental	Manipulation of one variable to see its effect on another variable, while controlling for as many other variables as possible and randomly assigning subjects to groups	Double-blind random assignment control groups, response to an intervention

(*continues*)

TABLE 1.1 Types of Research (*continued*)

Type	Description	Example(s)
Clinical	Performed in the clinical setting where control over variables is quite difficult	Drug trials, therapeutic results
Applied	Designed to answer a practical question, to help people do their jobs better	Time use studies, evaluation of different types of interventions with the same purpose
Descriptive	Describing a group, a situation, or an individual to gain knowledge that may be applied to further groups or situations, as in case studies or trend analyses	Surveys, qualitative research, measurement of characteristics, response to phenomena
Laboratory	Performed in laboratory surroundings that are controlled	Basic science research

Data from Bailey DM. *Research for the Health Professional: A Practical Guide*, 2nd ed. Philadelphia, PA: FA Davis; 1997, xxii.

clinical research, applied research, descriptive research, laboratory research,[1] and outcomes research. These forms depend on many factors.

There are many study designs available to beginning investigators.[2] Some research does not require specialized knowledge or skills, such as counting how many patients have a particular diagnosis. Other research requires specialized skills and must follow an exact methodology, such as clinical drug trials (studies of new medications). The recording of experimental results and writing of research have unique requirements that must be learned, practiced, and perfected. For most, research is about phenomena that affect what is done. Research is about observation and interpretation of what is learned to answer the questions posed.

Research can be enjoyable and rewarding. At every level and in every format and design, research should add to knowledge. It is unlikely that any single piece of research will make headlines. However, answering questions and making small contributions to the more substantial body of medical knowledge is very satisfying. Health care at every level continually creates questions that need answers. Society has questions that need answers. Learning the research process offers the highest likelihood of finding those answers. One does not have to be a genius to do research. One does not have to be mathematically gifted. One must only have an interest. It is a process to be learned and used to help healthcare practitioners, patients, students, and others.

Developing a Research Project

If a research project is part of education and training, it may take many forms. Choosing a project and developing its design depend on several factors (1) knowing what is expected, (2) identifying clear parameters, and (3) following organizational guidelines. Many organizations prescribe a scientific writing format. Student investigators must know which style and style manual is required and should obtain a copy.

Schools or institutions may assign research topics and specific designs to follow. Development of a research project depends on many factors. Some introspection and consideration about time, effort, cost, resources, and ability are required for any project. This introspection must include an assessment of personal attributes, interests, resources, and expectations of self. Part of this assessment must consider strengths as a researcher and abilities to accomplish the project. Students and inexperienced investigators must be able to concentrate their research efforts to develop or use their expertise to the maximum benefit. It is better to be an expert in one small area than somewhat of an expert in several. Every beginning researcher needs mentors and collaborators. Students and beginning investigators should seek out people who have skills in their area of interest and ask for their help. They should explore the possibilities of collaborating with someone on their research as a learning activity. Another key element to a successful research effort is the allotment of adequate time for investigations. For students, time may be limited by schedules, class obligations, planned graduation date, and the like. A timeline for a research project should be created and followed.

Research is a systematic, organized process that goes through some sequential (or near sequential steps (see **FIGURE 1.1**). The first step in developing a research project is brainstorming. This activity should be as expansive as possible by making a list (by hand or on the computer) of everything of interest. Once these ideas are recorded, a short break of a few minutes or a few days should be taken (the key is *not* to think about the project for a short while). Then the list can be refined; new items can be added, and those that do not seem relevant can be eliminated. This process may be repeated more than once before a project is defined. A student, for example, may have an assigned topic, but there may be many ways to approach the assigned project. Once a list of possibilities has been developed, the refining process can be done in this way:

1. Make a list of everything of interest or questions to be answered.
2. Prioritize the list in the order of interests.
3. Make a second ordered list (from the first) of the things that are within the capabilities of the investigator.
4. Make a third ordered list (from the first) of the things that are important to the effort.
5. Make a fourth ordered list (from the first) of the things that are important to society, or health, or the particular profession.
6. Compare the lists. Items that appear at the top of all four lists should be prioritized and merged into a single list.
7. Make decisions about what can and cannot be accomplished. Mark off the things that cannot be done for financial or other reasons.
8. The topic that survives or is central to the lists is the basis of the research project. This topic represents a process of summation that includes challenges that need to be researched; challenges to the capability of the researcher; and challenges that are important to the individual, the program, and the topic of interest. What could be better?
9. Develop a timeline for the study; set aside research time and plan the step-by-step process.
10. *Get started*. Time passes regardless, do not hesitate to get started.

Summary

Whether one loves it, hates it, or would rather not think about it, research is a part of professional life in a healthcare career. Research provides the basis for all that healthcare providers do. Individual

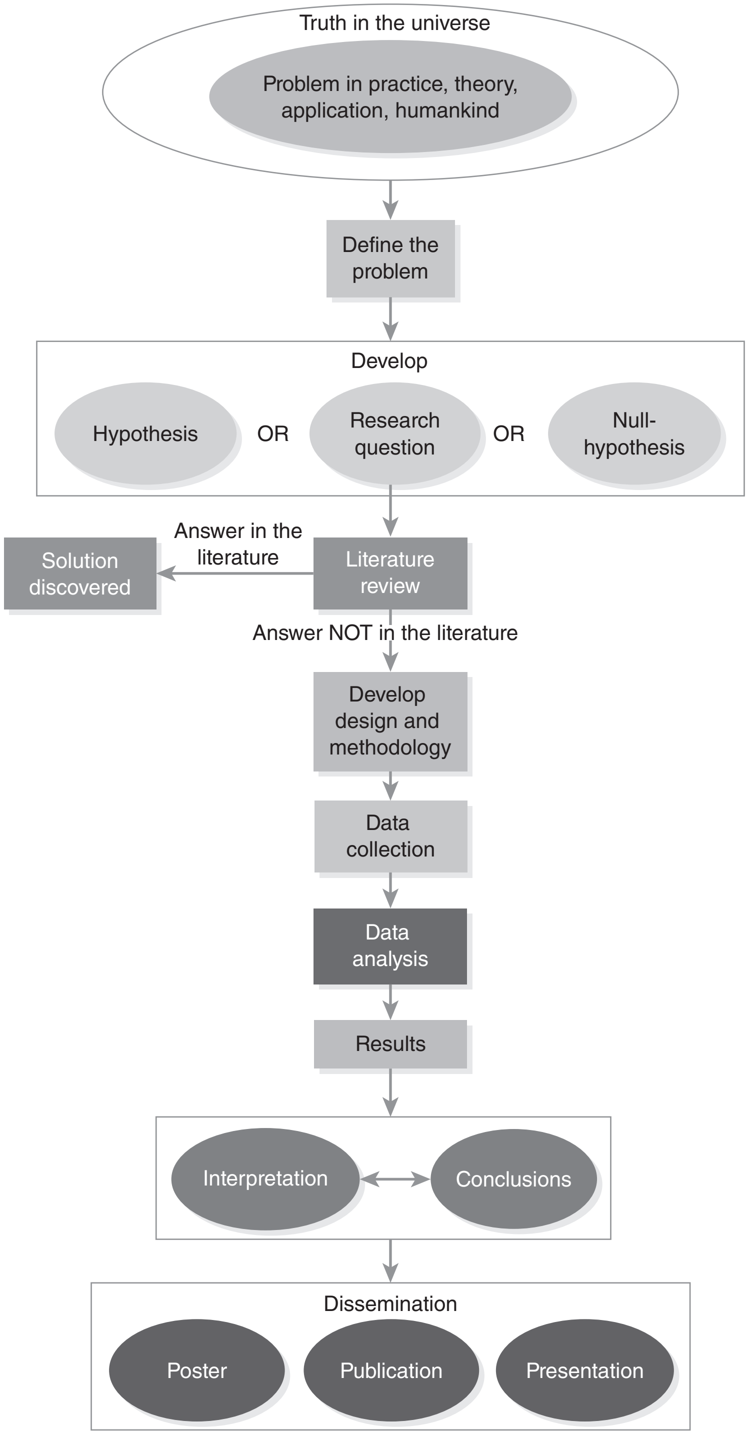
Truth in the universe
Problem in practice, theory, application, humankind
Define the problem
Develop
Hypothesis
OR
Research question
OR
Null-hypothesis
Solution discovered
Answer in the literature
Literature review
Answer NOT in the literature
Develop design and methodology
Data collection
Data analysis
Results
Interpretation
Conclusions
Dissemination
Poster
Publication
Presentation

FIGURE 1.1 Outline of the scientific process.

research is unlikely to change the world or win a Nobel Prize; however, each small addition to our knowledge of the world and health care improves them both. Remember is a powerful tool that every healthcare provider must learn to use and master to care for others.

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CHAPTER 2

Regulatory Protection of Human Subjects in Research

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CHAPTER OVERVIEW

The protection of human subjects in research is paramount to any research effort. Research that involves human subjects is highly regulated by federal, state, and institutional policies and requirements. Protection is extended to almost every type of research that involves people, even survey research. The purpose of this chapter is to provide historical context, explain the federal regulations that govern research involving humans, to clarify the authority of the institutional review board (IRB), and to address the responsibilities of investigators conducting research using human subjects.

LEARNING OBJECTIVES

- Describe, discuss, and define protection of human subjects.
- Describe and discuss the need for protection of human subjects.
- Outline and discuss the Belmont Principles.
- Describe the functions of the institutional review board.
- List the elements of informed consent.

Introduction

Health professionals commonly work on projects or other activities that involve data collection, analysis, and interpretation. The use of data to draw conclusions and solve problems is usually defined as research; however, many activities considered research (e.g., quality improvement,[1] program evaluation, scholarly and journalistic activities, public health surveillance, etc.) may not qualify as "regulated research" that requires the approval of an IRB. Although these activities share many of the data collection and analysis methods used by researchers, the outcomes serve different purposes. For example, nonregulated research activities produce results to be used internally or locally to influence immediate change. In contrast, regulated research results are widely applicable and not used to influence immediate change to the local organization or community. Health professionals must determine if a particular activity is regulated research and whether it requires the approval of the IRB. After reading this chapter, the reader should have a basic understanding of human research, how such research is regulated, and what responsibilities the researcher has when conducting a regulated research project.

Historical Context

Why are IRBs and regulation necessary? The answer is simple; history says so.

Researchers have not always treated their human subjects (some prefer "participants") appropriately. Unethical behavior finds its way into many human pursuits, and research is no different. People have been subject to research without their consent. Many have endured harsh treatments, and some have had fatal outcomes. Researchers have faked data and have submitted false research reports. The examples that follow illustrate why and how regulations protecting research subjects developed.

The Poison Squad

The poison squad.

Courtesy of the FDA.

Due to public outrage over descriptions of the meat packing industry in a book entitled the Jungle, by Upton Sinclair,[2] Congress passed the Food and Drug Act of 1906. Before the act, commercial food preparation was largely unregulated. Some government officials were concerned about preservatives and colorings in food. The Department of Agriculture's Chief Chemist, Harvey Wiley, recruited unmarried men to eat food contaminated with borax, salicylic acid, sulfuric acid, sodium benzoate, and formaldehyde.[3] These 12 men became known as "the poison squad." The men agreed to eat contaminated food for at least 6 months and waived any liability for damages.[3] In return, they received free food.[3] For 5 years, the purpose of these human feeding experiments was to see if preservatives were toxic to the human body. Ultimately, the Food and Drug Act of 1906 limited interstate commerce of the adulterated foods.[4] However, this initial legislation did not apply to ineffective and dangerous drugs.

In 1937, the Massingill Company produced Sulfanilamide, an antibiotic liquid containing diethylene glycol (antifreeze). The product killed 107 people.[5] The FDA was powerless to remove the product based on safety concerns—they could only remove a product for mislabeling. Public outrage once again resulted in a congressional response. The Food Drug and Cosmetic Act of 1938 was passed.[6] This legislation allowed the FDA to remove unsafe food and drugs from

ELIXIR
SULFANILAMIDE
THE S. E. MASSENGILL COMPANY
BRISTOL, TENN.-VA.

Sulfanilamide.

Courtesy of the FDA.

the market. Finally, in 1962, the drug thalidomide, an antinauseant taken in pregnancy, caused congenital disabilities.[7] The babies were born with phocomelia, a condition that includes shortened or absent limbs. This episode led to the passage of the Kefauver-Harris Amendments.[7] The amendments required drug manufacturers to prove efficacy, in addition to safety. In combination, these events strengthened the research requirements the Food and Drug Administration (FDA) relies on to approve products used or consumed by the public.

Eugenics and Nazi Experiments

The term *eugenics* roughly means "well-born." Years before the genocide in Nazi Germany, a wave of social Darwinism began in the United States. Charles Davenport established the Eugenics Record Office in Cold Spring Harbor, New York.[8] The purpose of the office was to improve the human race through selective breeding, an example of positive eugenics. Families competed in contests of genetic purity.[8] Concurrently, the government developed restrictive immigration policies, passed laws against race mixing, and ordered forced sterilization—examples of negative eugenics.

FITTER FAMILIES FOR FUTURE FIRESIDES
Eugenic and Health Exhibit
AMERICAN ILLITERACY

1920 Fitter Families competition.

American Philosophical Society.

One famous example of forced sterilization was the case of Carrie Buck.[9] This woman was born "illegitimate" and placed into foster care. She was raped at age 16 by her foster parents' nephew and became pregnant.[9] Labeled "feeble-minded and promiscuous," she was committed to the Virginia Colony for Epileptics and required to undergo forced sterilization. The order was appealed to the U.S. Supreme Court (Buck vs. Bell, 1927).[10] The court ruled 8 to 1 in favor of compulsory sterilization to "prevent crime and other social ills."[10] Justice Oliver Wendell Holmes Jr. declared "three generations of imbeciles are enough."[10] Surprisingly, this Supreme Court case has never been overturned. Although most states have rescinded their forced sterilization laws, the Buck vs. Bell ruling means the government, in certain circumstances, can forcibly sterilize its citizens.[9]

In the 1930s and 1940s scientists were viewed with reverence and respect. They were considered trustworthy and beyond reproach. That view began to shift when the public learned of the horrific treatment people endured in Nazi concentration camps during World War II. Camp prisoners, young and old, were subject to cruel and deadly experimentation.

Much of it was criminal torture. The categories of Nazi medical experiments included

High altitude experiment at Dachau.

Harvard Law School Library. Nuremberg Trials Project.

treatment of war exposures and injuries, reconstructive surgery, infectious diseases, biochemical agents, and eugenics.[11] **TABLE 2.1** provides examples of the types of experiments performed in each category.

Once discovered, these horrific acts prompted the Nuremberg Code of 1947[12] to guide human research. The code outlined the following human research standards:

1. Consent should be informed, voluntary, and non-coercive.
2. Experiments should be useful and necessary.
3. Human experiments should be based on animal research.
4. Physical and mental suffering should be avoided.
5. Death and disability should not be expected.
6. Risk should not exceed the humanitarian importance.
7. Human subjects should be protected from remote harms.
8. Only qualified scientists should conduct research
9. Subjects should be free to end an experiment.
10. Scientists should prepare to end experiments.

TABLE 2.1 Examples of Nazi Human Experiments during WWII[11]

War Related
- Extreme cold exposure to study hypothermia and warming
- Atmospheric pressure chambers to study altitude effects
- Forced saltwater ingestion
- Simulated war wounds using, bullets, ground glass, wood fragments
- Induced abscesses

Reconstructive Surgery
- Bone breaking, bone transplants, bone grafting
- Soft tissue resection and grafting

Infectious Diseases
- Inoculation with viruses for vaccine creation
- Malaria experiments
- Intentional tuberculosis exposure

Biochemical Agents
- Poison gas exposures
- Induced chemical burns
- Testing of poisoned bullets

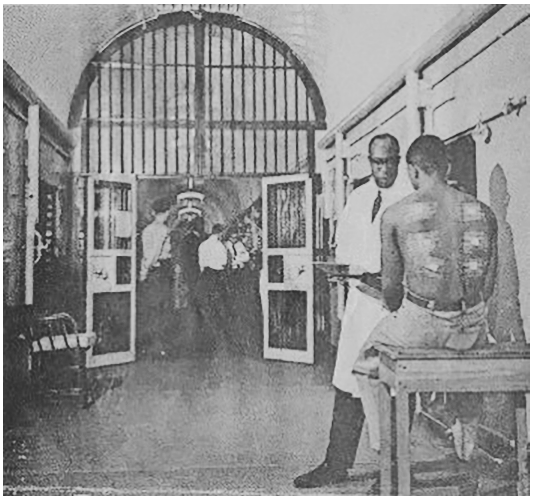
Eugenics
- Surgical sterilization and castration
- Intrauterine injections of iodine and silver nitrate
- Testicular and ovarian radiation exposures

Tuskegee Study of Syphilis

Public distrust of research is often rooted in such historical events. For 40 years, from 1932 to 1972, researchers from the U.S Public Health Service studied the pathophysiology of syphilis in 399 black males from Macon County Alabama.[13] Men in the Tuskegee Study of Untreated Syphilis (TSUS) were given physicals, hot meals, and burial stipends in exchange for their participation.[13] Although penicillin was available approximately 10 years after the study started, the investigators deliberately withheld treatment to observe the natural progression of the disease for an additional 30 years. The investigators took advantage of the low socioeconomic and educational status of the black men. Untreated, many suffered unnecessarily or succumbed to the disease.[13] When an Associated Press Reporter revealed the exploitation in 1972, mistrust of medical professionals by African Americans increased.[13] As a result of this mistrust, healthcare utilization declined, and mortality increased for black men, particularly in the south.[13] The TSUS example demonstrates the long-term consequences of unethical human research projects on vulnerable populations.

Holmesburg Prison Studies

Prisoners have also been subjected to research abuses. From the 1950s to the 1970s, investigators at Holmesburg Prison in Philadelphia studied how chemicals, including Dioxin, affected the skin of inmates.[14] These prisoners, who normally received 15 cents per day, were given up to $300 to participate.[14,15] For inmates who had no other income sources, the monetary amounts were an undue influence. The prisoners had a situational vulnerability that made them susceptible to coercion or undue influence. Other groups with a situational vulnerability include students, military personnel, and economically or educationally disadvantaged persons. In contrast, some groups have impaired decision-making capacity, lacking the ability to make informed decisions. Individuals in this category can include people with mental or cognitive disabilities.



Holmesburg prison skin testing.

Maicher, Michael J, Special Collections Research Center, Temple University Libraries, Philadelphia, PA.

In 1964, the World Medical Association produced the Declaration of Helsinki.[16] This statement of the ethical principles guiding human subject research has been amended several times. The declaration acknowledges groups that have an increased potential to be harmed by research. The most current version states "Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research."[16]

How Is Research Approved?

Before involving living individuals or their identifiable private information or biospecimens in regulated research, the institution's committee must review the research project and the protections provided. This committee is typically the IRB. The IRB is composed of scientists, nonscientists, and community members. Members of the IRB are selected based on their expertise in the types of research typically reviewed by the board or on the diversity of their background or experience. The goal of the IRB review is to ensure the individuals participating in the research are protected. To achieve this goal, the IRB reviews the written plan for conducting the research and the safeguards that will be provided to protect participants. The IRB must conclude that the research fulfills the basic principles for conducting ethical research established by the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research.[17]

In 1979, the National Commission released the Belmont Report, which established three fundamental ethical principles for conducting research involving humans.[17] (See **TABLE 2.2**.) The Belmont principles are respect for persons (autonomy),

TABLE 2.2 Belmont Principles

Respect for Persons

- Treat individuals as autonomous agents capable of making informed choices and acting on them.
- Individuals with diminished autonomy are entitled to additional protections.

Beneficence

- Maximize possible benefits and minimize possible harms.

Justice

- Fairness in the distribution of the benefits and burdens.

beneficence, and justice. Application of the general principles led to the development of the following requirements: informed consent, assessment of risks and benefits, and equitable selection of subjects. The National Commission was established by Congress in the National Research Act of 1974. The act requires researchers funded by the U.S. Department of Health, Education, and Welfare (now the U.S. Department of Health and Human Services [HHS]) to obtain IRB approval and informed consent. This regulation, 45 CFR Part 46, Subpart A,[18] became known as the Common Rule when it was adopted by 15 federal agencies in 1991.[19] The Common Rule was revised in 2017. In addition to the Common Rule, the FDA's regulations[20,21] for the protection of human subjects (21 CFR Parts 50 and 56) require IRB approval and informed consent for research involving drugs, devices, or biologics, regardless of the funding source. Finally, the Privacy Rule (45 CFR Part 164)[22] requires additional approval by a privacy board when research involves identifiable health information held by health-related entities, regardless of the funding source or whether the research uses a drug, device, or biologic. See **FIGURE 2.1**.

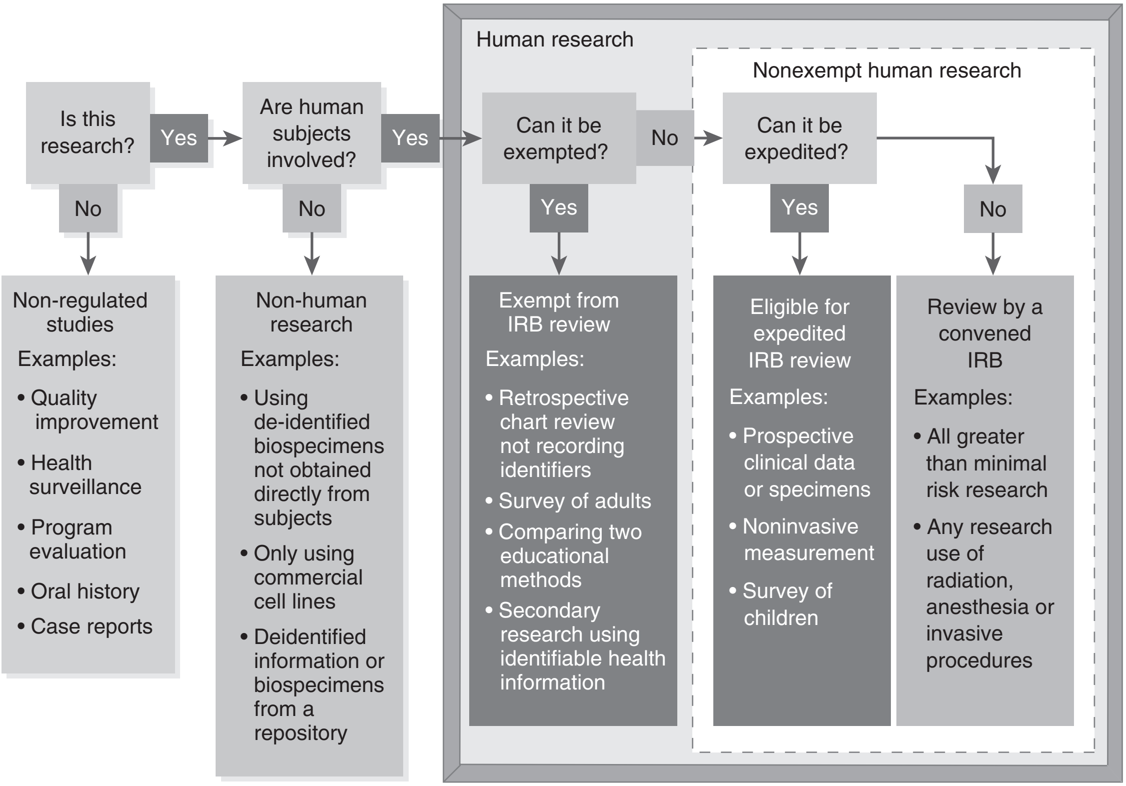

Human research
Nonexempt human research
Is this research?
Yes
No
Are human subjects involved?
Yes
No
Can it be exempted?
No
Yes
Can it be expedited?
Yes
No
Non-regulated studies
Examples:
• Quality improvement
• Health surveillance
• Program evaluation
• Oral history
• Case reports
Non-human research
Examples:
• Using de-identified biospecimens not obtained directly from subjects
• Only using commercial cell lines
• Deidentified information or biospecimens from a repository
Exempt from IRB review
Examples:
• Retrospective chart review not recording identifiers
• Survey of adults
• Comparing two educational methods
• Secondary research using identifiable health information
Eligible for expedited IRB review
Examples:
• Prospective clinical data or specimens
• Noninvasive measurement
• Survey of children
Review by a convened IRB
Examples:
• All greater than minimal risk research
• Any research use of radiation, anesthesia or invasive procedures

FIGURE 2.1 Determining whether human subjects are involved in research.

When Is IRB Approval Required?

IRB approval is needed whenever a project meets the regulatory definitions of human-subjects research provided in either the Common Rule[3] or the FDA regulations.[20,21] The Common Rule applies to most research conducted by healthcare professionals. Although the Common Rule is technically only applicable to federally funded or supported research, most institutions apply it to all human subjects research, regardless of the funding source. The Common Rule requires IRB approval of all "human-subjects research." Two questions help identify activities as human-subjects research:

- Is this regulated research?
- Are human subjects involved?

Is This Regulated Research?

The Belmont Report noted that the distinction between research and practice (non-research) is blurred. The Common Rule defines research as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."[18]

Unfortunately, the two key concepts in the definition—"systematic investigation" and "generalizable knowledge"—are not clear. The definition is not particularly helpful in defining regulated research because many other activities such as patient satisfaction surveys and ward infection surveillance would be considered systematic investigations. Generalizable knowledge should be interpreted as a matter of policy to mean "widely applicable." This interpretation has the advantage of meeting the common intuitive interpretation of "[regulated] research" and maximally carving out scholarly activities.[23]

In general, the purpose of research is to fill a gap in the current knowledge. The Belmont Report describes research as ". . . an activity designed to test a hypothesis, permit conclusions to be drawn."[17 (p4)] If the conclusions drawn from the activity are widely applicable, one could say the results are generalizable. Research activities that meet both parts of the definition (systematic and generalizable) are considered to be regulated research.

Are Human Subjects Involved?

When it has been determined that an activity meets the regulatory definition of research, the next step is to decide whether the research involves human subjects. Regulated research involves human subjects if the researcher either obtains information or biospecimens through interacting or intervening with a living individual or obtains, uses, analyzes, or generates private identifiable information or identifiable biospecimens about a living individual. Interacting means the researcher communicates or has interpersonal contact with the individual (e.g., makes phone contact for recruitment or obtains consent to participate). Intervening includes physical procedures (e.g., obtaining blood), manipulating the individual (e.g., providing a treatment), or manipulating the individual's environment (e.g., changing room temperature). Information is considered private when it is provided for a specific purpose by an individual, and the individual can expect it will not be made public. Private information is considered individually identifiable if the identity of the individual may be ascertained by the investigator or associated with the information. Whether or not an activity meets these criteria, it is still necessary to consider whether it is research under the FDA human protections regulations.[20]

Is This FDA-Regulated Research?

Although it is uncommon for students and practicing professionals in healthcare professions to conduct research that is FDA regulated, FDA regulations should be considered to determine if IRB approval and informed consent are required. The FDA often uses the term *clinical investigation* to indicate research. FDA-regulated research includes the following[24]:

- Use of an unapproved drug or biologic
- Use of an FDA-approved drug other than the use of a marketed drug in the course of medical practice

- Use of a device to evaluate safety or effectiveness of that device
- Submission of data from the use of a drug or device to the FDA for advertising or a change in labeling.

If a study involves any of these, the investigator should contact the IRB for guidance. Not only will IRB approval and informed consent be required, but additional FDA permissions may be necessary before the research can begin. If the activity meets either the Common Rule or FDA definition of human subject research, it will be reviewed by the IRB unless it qualifies for an exemption to the Common Rule.

Can It Be Exempted?

If a regulated human-subjects research project is not subject to the FDA human protection regulations (as described previously) and is not aimed at involving a prisoner population, it may qualify for exemption from the Common Rule.

Certain regulated human research studies that involve very little or no risk and fall entirely within one or more specific exemption categories (as defined in the regulations) may qualify for exempt status. This status means that the institution is not required to follow the Common Rule with respect to the research (e.g., obtain IRB approval).[25] However, other rules may apply to an exempt study. In general, the institution or a higher authority establishes policy for approving/overseeing exempt human research. For example, because IRB approval is not required, most institutions designate an office or official to determine that the research is exempt. Currently, the Office for Human Research Protections (OHRP, a subdivision of HHS) does not recommend that investigators be given the authority to make an independent judgment. Most local policies applicable to exempt research follow the Belmont Principles. (The IRB should be consulted for specific guidance.)

Examples of the most common types of research that can be exempted include (1) research involving normal educational practices such as comparing different instructional curricula or techniques not likely to adversely affect the student or educator, (2) surveys (not involving children) that collect information that would not likely pose a risk to those completing the survey if their answers were released (either because the information is not sensitive in nature or because it cannot be traced back to the individual), or the IRB has conducted a limited review and has determined if identifible information is recorded there are adequate protections to ensure confidentiality of the data, (3) chart reviews of health information that is either not traceable back to the individual or when identifible health information is collected it is regulated by HIPAA, or (4) research involving benign behavioral interventions (not involving children). An institution's IRB provides the complete list of exemptions from the Common Rule.

If a research project does not meet the criteria for exemption (nonexempt regulated human-subjects research), it must be reviewed by the IRB. In reviewing nonexempt regulated research, the IRB can use one of two review processes: (1) expedited review or (2) review by a meeting of the IRB.

Can It Be Expedited?

Some nonexempt studies that involve only minimal risk to participants and fall entirely within one or more specific expedited categories may be eligible for an expedited review procedure. The IRB chairperson or one or more experienced members of the IRB may carry out an expedited review instead of full board review. It is necessary to understand the concept of risk when determining if a study is eligible for expedited review.[18] Risk is a measure of harm. It refers to both the likelihood (i.e., probability) that harm may occur and the magnitude of possible harm. Although investigators often focus on physical harms when developing their IRB application, the IRB views harm more broadly. Harm can be categorized as physical (e.g., injury or pain), psychological (e.g., anxiety or shame), social (e.g., adverse effect on relationships), economic (e.g., financial costs), legal (e.g., arrest or lawsuits), or dignitary (e.g., violates personal values).[19]

Like the regulatory definition of human-subjects research discussed earlier, the meaning of minimal risk is a source of debate and may be defined differently by different IRBs. In general, minimal risk means the risks from research activities are not higher than those ordinarily encountered in daily life. Recognizing the debate over whether daily life should be taken to refer to an absolute (i.e., daily life of healthy individuals) or relative (i.e., the daily life of participants of the research), many IRBs consider any activities outside those conducted during a routine physical or psychological examination as carrying more than minimal risk.[18,20] Examples of minimal-risk procedures that meet this definition include simple venipuncture, physical examinations, magnetic resonance imaging (MRI) procedures (not involving contrast), surveys or interviews, and the like. Studies that fall within one of the expedited review categories are presumed to be minimal risk by the regulations.

The categories of research eligible for expedited review include the following[18,21]:

1. a. research on approved devices that will be used in their approved manner;
   b. the study of approved drugs in a manner that does not increase the risk or decrease the acceptability of the risk associated with the use;
2. collection of blood in limited quantities over specific time periods;
3. noninvasive collection of biological specimens (e.g., urine, leftover specimens collected for other purposes);
4. noninvasive data collected routinely in clinical practice that do not involve x-rays, general anesthesia, or sedation (e.g., MRI, weight, blood pressure);
5. use of information or specimens that have already been collected for any purpose or use of information or specimens that will be collected solely for non-research purposes (e.g., medical record reviews);
6. recordings (e.g., voice recordings, digital images);
7. and surveys, focus groups, or interviews.

It is important to remember that all research procedures must fall into one or more of the expedited categories. An example of a research study that may involve minimal risk but does not fall completely within the expedited review categories is a study involving the use of health information routinely collected as part of routine dental care and a dental x-ray is obtained for research purposes. The dental x-ray procedure does not fit any of the expedited review categories (i.e., noninvasive data collection is not appropriate because this procedure involves x-rays). Therefore, although the risk to the participants may be minimal, the research study is not eligible for expedited review (at least initially) and would be reviewed by the convened IRB. If the convened IRB determines the study involves no more than minimal risk, future IRB reviews of the study may be completed using the expedited review procedure.

What If a Research Project Is Not Eligible for Expedited Review?

The convened IRB (i.e., the full committee) must review regulated research that does not meet criteria as either exempt or expedited. A convened IRB is a committee of at least five members, each with varying background, expertise (scientific and non-scientific), diversity, and affiliations (both affiliated and not affiliated with the institution).[18,21] Notably, the IRB uses the same criteria for evaluating a study regardless of whether it is reviewed by expedited review or the convened IRB. The Common Rule and the FDA human-protection regulations impose specific criteria for approval of regulated research. Investigators should develop the study plan with the specific criteria in mind. Many investigators assume their scientific plan is the only information the IRB needs to approve their research. Although there are significant overlaps, they are not the same. In general, the IRB application calls for additional information not commonly found in the grant application or academic degree proposal. The criteria used by the IRB to approve regulated research are presented in **FIGURE 2.2**.

How Will the IRB Review a Regulated Research Project?

For the IRB to approve research, it must determine the following:

> *The risks to the participants have been minimized.* The probability and

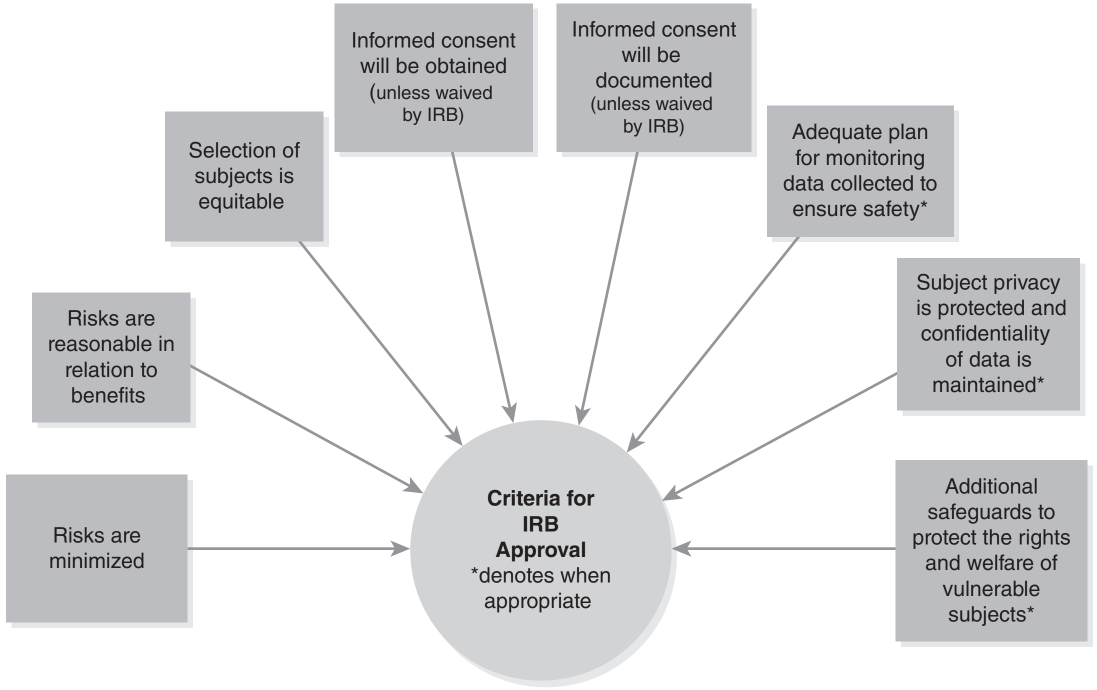

Selection of subjects is equitable
Informed consent will be obtained (unless waived by IRB)
Informed consent will be documented (unless waived by IRB)
Adequate plan for monitoring data collected to ensure safety*
Risks are reasonable in relation to benefits
Subject privacy is protected and confidentiality of data is maintained*
Risks are minimized
Criteria for IRB Approval
*denotes when appropriate
Additional safeguards to protect the rights and welfare of vulnerable subjects*

FIGURE 2.2 Criteria for IRB approval of nonexempt regulated research.

magnitude of the reasonably expected research harms have been minimized. However, the nature of the study may limit the extent to which risks can be minimized. Some ways researchers can minimize risks are by choosing a procedure that would pose less risk to the participants over another or designing the study to use procedures that would be performed regardless of whether the individual was enrolled in the research.

The risks are reasonable compared to anticipated benefits. In general, research can potentially benefit individual participants (direct benefit) and/or society (essential knowledge gained). An assessment of risks to potential benefits is often referred to as a risk–benefit ratio. The IRB will approve only research where the probability of a benefit outweighs the risks of participating in the research.

The selection of subjects is equitable. With a clear understanding of the risks and potential benefits of the study, consider whether the selected population fairly distributes the burdens and benefits of the research. In making this determination, the IRB considers whether the study targets individuals who will likely benefit from the outcome of the research. For example, the board may ask whether there are participants who may benefit more from the study.

Informed consent will be sought from each prospective subject or the subject's legally authorized representative. Because informed consent is one of the three basic protections provided by the Common Rule, the IRB will require it in most cases. The human-protection regulations define the basic information that must be provided while obtaining informed consent (see **TABLE 2.3**). In some cases, a request may be made that some or all of the elements of consent be waived by the IRB. For example,

TABLE 2.3 Elements of Informed Consent

Essential elements of informed consent provide participants with the following information:

A statement that the study involves research

- An explanation of the purposes of the research
- The expected duration of the participant's participation
- A description of the procedures to be followed
- Identification of any procedures that are experimental

Description of any reasonably foreseeable risks or discomforts

Benefits that may reasonably be expected

- To the participants (if applicable)
- To others

Alternative procedures or treatment, if any, that might be advantageous to the participant

Confidentiality of records

- The extent, if any, to which confidentiality will be maintained

Injury-related care or compensation (for research involving more than minimal risk)

- Whether any compensation and medical treatments are available if an injury occurs
- If so, what they consist of, or where further information may be obtained

Contact information: Whom to contact

- For answers to pertinent questions about the research and participants' rights
- In the event of a research-related injury to the participant

Participation remains voluntary—no penalty or loss of entitled benefits

- By refusing to participate
- By discontinuing participation at any time

If identifiable specimens are collected, a statement on whether if subsequently de-identified the specimens will be used for future research or not.

Additional information when determined to be appropriate by the IRB

- A statement that the particular treatment or procedure may involve unforeseeable risks
- Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent
- Any additional costs to the participant that may result from participation in the research
- The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the subject
- A statement that significant new findings developed during the research that may relate to the participant's willingness to continue participation will be provided to the subject
- The approximate number of participants involved in the study

Additional informat ion when research involves biospecimens:

- Statement whether specimens may be used for commercial profit and if subjects will share in the profit
- Statement whether clinically relevant research results will be disclosed to subjects and if so under what conditions
- Statement whether research might include whole genome sequencing

a waiver of all elements of consent may be appropriate for a study using existing health information that was collected for clinical purposes where it is not feasible to obtain consent from the individual patients. An example of an alteration of informed consent (omitting some elements) would include a study where some of the required information is not appropriate for the research. In this case, the investigator can request an alteration in consent if the study meets the criteria for alteration of consent. In addition to the information provided during the consent process, the IRB also evaluates the researchers' plan for obtaining informed consent. A recruitment plan should provide ample opportunity for prospective participants (or their legally authorized representative) to make an informed choice. Considerations include the study setting, how and by whom the consent interview will be conducted, and timing for obtaining consent (to minimize the possibility that prospective participants may perceive undue pressure to enroll or feel coerced).

The informed consent will be appropriately documented. The investigator must have definite plans for obtaining appropriate signatures of participants (or their legally authorized representative) to document the informed consent process. Most IRBs provide a consent document template that provides the essential elements of consent. If this documentation is not possible (e.g., telephone surveys), the investigator may request a waiver of documentation of informed consent, which must be approved by the IRB. In these situations, the researcher must make a note in the research record that all of the required information (see Table 2.2) about the study was presented to the participant and the participant willingly agreed (consented) to participate in the research.

The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects (when appropriate). When required, a plan for monitoring the safety of the study using the data collected should be developed. This plan should include (1) how often safety data are compiled and reviewed, (2) by whom (an individual or committee), and (3) whether limits are needed for stopping the research procedures to ensure the safety of the participants. A formal monitoring plan is usually required for FDA-regulated clinical trials, all National Institutes of Health (NIH) funded research and more than minimal risk research.

There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data (when appropriate).[26] For example, assigning study codes to participants rather than using names and storing the key to decipher the codes in a separate, secure location accessible only to the investigators is a way of demonstrating this type of protection.

In addition to the seven determinations just listed, if a study involves populations vulnerable to coercion or undue influence, such as children, prisoners, or individuals with impaired decision-making, the IRB will be particularly cognizant of the special problems of research in these populations. The IRB will also evaluate whether the study provides additional safeguards capable of protecting the rights and welfare of pregnant women, fetuses, and neonates, prisoners, and children.

In preparing a research project for review by the IRB, the study plan should be designed with the required IRB determinations in mind. Although it is the IRB's responsibility to determine whether these requirements for approval are met, it is the investigator's responsibility to design and carry out the study plan in such a way that the criteria for approval are met. This compliance activity is one of several responsibilities assumed by the investigator responsible for the research.

What Are the Investigator's Responsibilities?

Obtaining IRB approval for a new project is only the first of many responsibilities for the principal investigator (PI).[27] During the conduct of the study, the PI must ensure the study continues to meet the criteria used by the IRB for the initial approval.[28] The PI is also responsible for communicating regularly with the IRB under certain circumstances such as those described in the following sections.

Continuing Review

Many investigators do not realize that some IRB approvals they get when a study is first reviewed by the IRB has a time limit that cannot exceed one year (e.g., studies that are greater than minimal risk). To request reapproval so that the research can continue uninterrupted, the PI must submit a status report to the IRB before the approval period expires. The report must include:

1. information about the number of participants accrued (if any);
2. a description of any adverse events, unanticipated problems, participant withdrawals, or complaints;
3. a summary of relevant new information (either published or learned in the research); and
4. a copy of the current consent document(s) being used.

The IRB reviews the status report, including any other new information, and reconsiders the required determinations for approval of research. If the study continues to meet the criteria for approval, the IRB will re-approve the study for up to 1 additional year.

Sometimes, the IRB may decide to issue an approval for less than a year (e.g., for unusually high-risk studies the IRB may approve the study for only a few months). It is the responsibility of the investigator to contact the IRB to request reapproval before the expiration of the original IRB approval.[27] If the IRB has not reapproved a study that requires continuing review before the current approval period expires, research procedures may not be performed.

Some research reviewed by the IRB may not require continuing review (e.g., research eligible for expedited review, research that has progressed to a point that only involves data analysis, research that has progressed to only accessing follow-up clinical data obtained as part of routine clinical care). There may still be some reporting requirements to the institution for these types of activities outside of the IRB regulations.

Modifications

When changes to a research study are needed, IRB approval must first be obtained before the modification is implemented.[27] Changes may be made to a study without prior IRB approval only when the modification is necessary to eliminate an immediate hazard to the participants. Examples of changes that must be approved by the IRB are changes in the number of participants needed to enroll; changes to the study design, methods, or procedures; changes to study sites or locations; changes in consent procedures and/or consent document; changes in recruitment materials; and changes in compensation amounts. Each IRB establishes a mechanism for requesting approval of modifications. Like new studies, the IRB may use expedited or full-committee review procedures. Minor changes to already approved studies are eligible for expedited review.

Tracking Adverse Events and Reporting UPIRSOs

Adverse events can be expected in research. A good data safety monitoring plan allows investigators to track adverse events that occur during a research study and to continuously monitor them to determine whether changes should be made to the research plan to minimize risks to participants.[29] Although adverse events should be tracked, not all occurrences must be reported to the IRB immediately.

Only adverse events that meet the criteria of an Unanticipated Problem Involving Risks to Subjects or Others (UPIRSO) must be reported immediately to the IRB. An UPIRSO is any incident, experience, or outcome that meets *all* of the following criteria[29]:

1. Unexpected (regarding nature, severity, or frequency);
2. Related or possibly related to participation in the research; and
3. Suggests that the research places participants (or others) at a higher risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Although some UPIRSOs are also adverse events, keep in mind that not all UPIRSOs are adverse events. UPIRSOs may result from other problems such as the unintentional loss of identifiable private information that represents an increased likelihood of harm, rather than actual harm. The IRB will review the UPIRSO and determine whether the research should continue and whether modifications should be made to the research to offer additional protection to the participants or others.

Reporting Noncompliance

The PI should report instances of noncompliance to the IRB. Noncompliance is an action by the investigator or member of the research team that disregards or violates federal regulations, IRB requirements and determinations, or institutional policies and procedures.[27] When noncompliance is discovered, the IRB reviews the events surrounding the incident; the seriousness of the event and whether it has occurred before; and the event's effect on the participants' rights, welfare, and safety. The IRB often requires a written report from the investigator that includes a corrective action plan. The IRB may decide that additional actions are necessary to address the noncompliance; such actions may range from retraining the PI or study staff to suspension or termination of the research (depending upon the severity of the event). If the IRB determines the noncompliance is either serious or continuing, the event is reported to the OHRP (for research funded by HHS) and/or the FDA (for certain FDA-regulated research).[18]

Inactivation

The investigator should notify the IRB when approved studies that require continuing review have concluded or when the IRB approval is no longer necessary. The investigator notifies the IRB of the intent to inactivate the IRB approval by providing a final status report to the IRB. The IRB reviews the status of the study and determines whether inactivating the approval is appropriate.

Additional Responsibilities

In addition to the responsibilities of the investigator to the IRB as outlined in the previous sections, the following additional responsibilities are expected of PIs[30,31]:

- Complete and maintain training on human-subjects protection. Each institution has its specific training requirements. (Several courses are available on the Internet.)
- Follow the IRB-approved protocol and the regulations and policies related to research and privacy.
- Supervise project workers to ensure they follow the protocol and rules that govern research.
- Place the protection of research participants first.
- Verify IRB approval before allowing research to begin or before implementing changes.
- Keep participants informed and ensure they are willing to continue participating.
- Ensuring informed consent occurs at the beginning of research participation and continues throughout a participant's involvement in the research.
- Regularly collect and assess information about safety or unexpected problems.

- Conduct regular literature reviews for new information that may affect the study or the study participants.
- Ensure those working on the project are qualified and are authorized, by education, training, experience, and certifications, to perform delegated tasks.
- Provide ongoing communication with study staff. This communication allows the PI to assess problems as they arise and to make swift changes as necessary.
- Confirm that the data collected are accurate.
- Maintain organized records.

By following these guidelines, the PI protects research participants and improves the quality of the research conducted.

Summary

In conclusion, some complex federal regulations govern research involving human subjects. This chapter provided a historical rationale for these protections. It also introduced the major concepts involved in complying with regulations. Health professionals must understand the basic ethical principles that guide research and their responsibilities to comply with the rules and regulations applicable to the type of research they may conduct. Investigators and their IRBs must work together to ensure that research is conducted safely and ethically. When planning any regulated human-subjects research project, the investigator should contact the local IRB for assistance.

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CHAPTER 3

The Research Problem

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CHAPTER OVERVIEW

This chapter discusses the development and refinement of the research problem. Developing a research question, hypothesis, or null hypothesis is sometimes challenging. Identification of the research problem and defining it in terms that can be investigated and studied is a critical step in the research and scientific process. A well-defined research problem, properly formated, will drive the research methodology. Defining the research problem and developing a research question, hypothesis, or null hypothesis requires effort and time. Students in healthcare professions must be able to define research projects by formulating a research question, hypothesis, or null hypothesis. The way the research problem is defined depends on how the problem is framed. This can present a challenge.

LEARNING OBJECTIVES

- Describe where research problems originate.
- Define what constitutes a research problem.
- Develop a research problem list.
- Identify a research problem.
- Define and describe the need to study a research problem.
- Develop a research question, hypothesis, or null hypothesis for a research problem.

Introduction

Research provides a systematic process for uncovering answers to clinical and other questions. Research also expands on current knowledge that can be applied to education and clinical practice. Although some problems may be evident, others are not as easily recognized or defined. When a problem or question is identified, it must be defined in a format that allows for successful study. To the novice, this may be the most challenging step. It is essential to ground the inquiry in practice.[1]

So, how does a healthcare professional go about identifying a problem for research? This involves more than just asking or writing down a question; it is a mental exercise that requires stepwise movement from general to more specific concepts, thereby focusing on and defining the question as explicitly as possible.[2]

Why go through the mental exercise and invest time before beginning a research project? Because determining the right researchable question or statement will define the problem effectively and accurately, thus setting the tone for the entire exploratory process and subsequent work. Generally, healthcare professionals investigate problems that interest them or impact their work and clinical care. Passion about the topic will sustain the research during all phases of the project.[2]

Identifying the research problem is not always a simple task because every problem has compounding factors that can interfere with what needs to be studied. This challenge is particularly real for those who are new to research. For many investigators, getting to the exact problem to be studied is like looking through foggy glasses or a smudged windshield. Without a clear focus (that is, a well-defined research question) the process is confusing, frustrating, time-consuming, and wasteful. In fact, failure to develop a clear, concise, and defined research problem can lead to unsuccessful research. Think of the research problem as the guiding light that points the investigator in the right direction. Until the fog has dissipated, or the windshield has been cleaned, the view remains unclear.

The Process

How are topics selected? Generally, the topics of interest come from the environment, work, or interest in a particular subject or problem.[1] Sometimes the literature creates a topic that needs further investigation; some research articles generate more questions than they answer. By reviewing the work of others, healthcare professionals can advance the conversation. Sometimes, furthering the conversation involves the expansion of ideas. In other cases it involves "pruning" or refinement of prior work.[3]

Study replication (doing the same investigation to confirm or refute findings) can be an exciting adventure and may lead to confirmation of findings or perhaps new findings. Published work may lead an investigator to research a similar problem in a group or area not covered by the first study. Questions about study methodology or an author's conclusions can lead to new studies and research replication. Replication is an excellent way to determine whether findings are applicable in a different clinical setting or practice. Replication can confirm or repudiate study findings or redefine previous study results or conclusions.

In general, existing knowledge or prior experience in a specific field is necessary to discern what research needs to be done. Researchers must be sufficiently knowledgeable about what has been accomplished, where current knowledge stands, and where to go next. A preliminary literature review and search is conducted to examine current information and to help further define the problem or research question. Otherwise, the problem will remain unclear as long as there is uncertainty about the nature of the issue or problem. Knowledge of previous research is key to developing a project that will genuinely explore a problem. New understanding or knowledge must be built on what has gone before. Researchers who do not consider what has been done before may repeat what has been done and add nothing to the fund of knowledge. Research done without awareness of previous studies and existing data is a waste of time and effort. The research problem needs to be defined by a literature search that explores what is known and aids in defining what is not known.

What Constitutes a Research Problem?

A research problem may be viewed as a situation that begs resolution or needs improvement, modification, or an answer. In other words, it is a situation that warrants examination and study, whether to do things more effectively or to validate observations made in the classroom, clinic, or another setting. Alternatively, the research problem could be something in which a healthcare professional is curious or interested.

An example of a research problem that is often studied in the healthcare professions is the identification of factors that determine patient satisfaction with care. This satisfaction might deal with a particular profession or satisfaction within a specific practice or setting. A similar and related problem of interest is the contrast among patient satisfaction with care provided by different types of providers. Another example of a research problem is identifying the factors that affect patient adherence to treatment regimens. These influences could be religious beliefs, cultural beliefs and ethnic standards, socioeconomic factors, or the like. These problems are interesting to others, both within and outside the healthcare environment. For the researcher, the results are the results. Results are accepted, even if they do not reflect what the investigator believes or thinks.

TABLE 3.1 summarizes the various origins of research topics.

TABLE 3.1 The Origin of Research Topics

- Work environment (clinical observations, problems, or challenges)
- Personal interest (medical condition of self, family member, or acquaintance)
- Prior studies (journal articles or reports in medical and lay literature)
- Mentor, preceptor, or teacher interest
- Literature review
- Studies by others
- Graduation requirements

Getting Started

One way to get started on a research endeavor is to take a few moments to list some problems or questions for which solutions or answers are needed. **BOX 3.1** offers one way to prioritize the questions. Keep in mind that substantive research is not accomplished overnight. Research can be a lengthy process and has the potential to become tedious and frustrating. Investigators sometimes have to work to maintain enthusiasm for their research, but without continued enthusiasm, goals are not likely to be met.

BOX 3.1 Prioritizing Research Questions

Exercise: List five research problems of interest (see TABLE 3.1). Rank the degree of interest in each (most interesting = 5; least interesting = 1).

Problem	Rating
1. ____________________	________
2. ____________________	________
3. ____________________	________
4. ____________________	________
5. ____________________	________

How to Identify a Research Problem

Identifying the research problem is the first step in conducting research. It begins by asking: What is the question to be answered? It is a good idea to write down questions to begin the recordkeeping for a study. Every researcher must be able to manage problems because having a large number of problems in a single study can hinder its success. Remember, "keep it simple." It is best to identify a problem in its basic form and to do a thorough investigation of that problem rather than tackle a large number of problems. This aspect is analogous to a predator that becomes successful only after it has learned to identify and focus on the appropriate prey. A successful predator chases one prey, not the whole herd. Otherwise, the adverse outcome of the chase is a foregone conclusion, and the predator is left hungry. The same is true for identifying research problems. One well-identified and well-defined problem is much better than some ill-defined or general problems. It is worth remembering that it is unlikely that an earth-shattering discovery will be made, but each investigation can add a small piece to the more substantial body of knowledge.

A healthcare professional determined to investigate a problem must be able to focus on what needs to be done to resolve the problem (or situation) at hand. To further define the problem, several useful questions can be posed along the following lines:

- Given a problem, what can be done or what approach should be taken to improve it?
- What is known (what does the literature say) about the problem?
- What is not known about the problem (the literature gap)?
- What information or data are needed to improve the situation?

Based on answers to these and other questions, the problem(s) should become better defined.

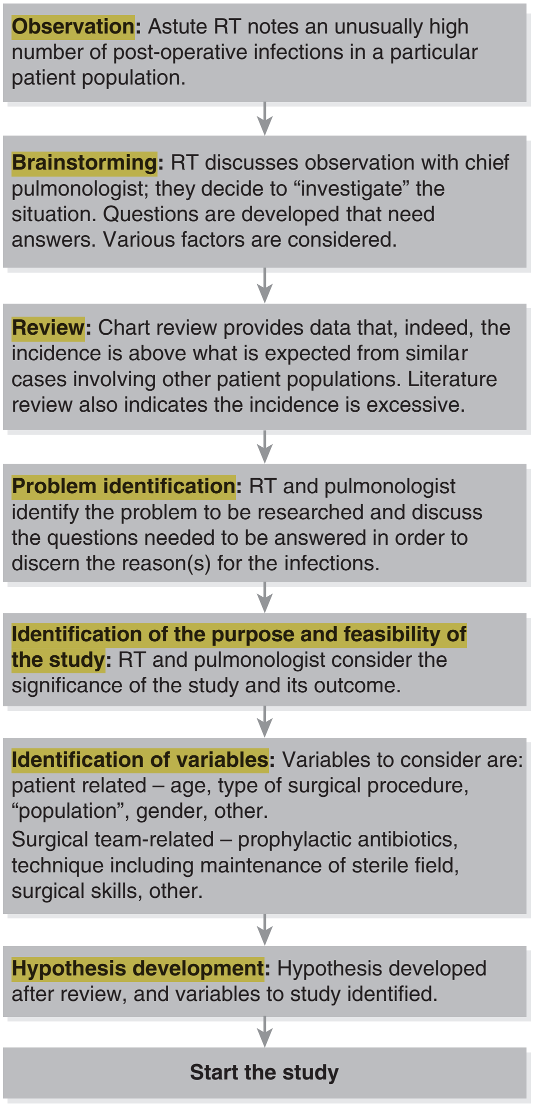
Consider the following as examples of a process for development of a problem and study:

Scenario 1. A respiratory therapist (RT) is keeping a log of patients who are on ventilators. She notes an unusual number of postoperative infections in patients needing postoperative ventilation. The RT discusses this observation with the chief of pulmonology. After perusing several patient charts, the two concur that the problem is real and decide "someone should look into it" to determine the reason for these infections and ultimately minimize the number of postoperative infections. In this case, determining the reason for the infections is the purpose of the study, and minimizing the number of postoperative infections is the goal of the study. Other reasons for performing the study include reducing morbidity and mortality, reducing the costs of care, and other equally important goals, such as improved patient outcomes and, maybe, patient satisfaction.

The RT and the pulmonologist then devote time deciding what to do (brainstorming), and they formulate questions to narrow the focus, determine the importance of the study, and decide the degree to which an investigation can be done. They consider, among others, the following questions:

- What information needs to be gathered?
- Where can the information be accessed?
- Will the investigators rely only on medical records or will they include survey data from patients, nursing staff, or others?
- What, if any, consents need to be obtained from patients and the institutional review board (IRB)?
- Will the investigators recruit a consultant to help design the study or analyze the data? If so, whom?
- Should the results be published, and if so, in what medium (i.e., how should the information be disseminated)?
- What are the ethical issues, and how will they be addressed?
- Where can the investigators find financial support to perform the study?

FIGURE 3.1 is a schematic of the process of developing a hypothesis from an observation based on this scenario.



Observation: Astute RT notes an unusually high number of post-operative infections in a particular patient population.

Brainstorming: RT discusses observation with chief pulmonologist; they decide to “investigate” the situation. Questions are developed that need answers. Various factors are considered.

Review: Chart review provides data that, indeed, the incidence is above what is expected from similar cases involving other patient populations. Literature review also indicates the incidence is excessive.

Problem identification: RT and pulmonologist identify the problem to be researched and discuss the questions needed to be answered in order to discern the reason(s) for the infections.

Identification of the purpose and feasibility of the study: RT and pulmonologist consider the significance of the study and its outcome.

Identification of variables: Variables to consider are: patient related – age, type of surgical procedure, “population”, gender, other.
Surgical team-related – prophylactic antibiotics, technique including maintenance of sterile field, surgical skills, other.

Hypothesis development: Hypothesis developed after review, and variables to study identified.

Start the study

FIGURE 3.1 Schematic diagram of developing a hypothesis from an observation.

Some examples of possible research questions for this particular scenario include the following:

- Are there procedural differences between infected patients and noninfected patients?
- Are there demographic differences between infected and noninfected patients?
- Are there care differences between infected and noninfected patients?

Using the null-hypothesis format, these questions would be considered about the following statements:

- There are no procedural differences between infected and noninfected patients.
- There are no demographic differences between infected and noninfected patients.
- There are no care differences between infected and noninfected patients.

Using the hypothesis format, these questions would be considered about the following statements:

- There are procedural differences between infected and noninfected patients.
- There are demographic differences between infected and noninfected patients.
- There are care differences between infected and noninfected patients.

Using a research question format, these questions would be considered about the following statements:

- What are the procedural differences between infected and noninfected patients?
- What are the demographic differences between infected and noninfected patients?
- What are the care differences between infected and noninfected patients?

Which format should be used? Indeed, the research question is broad and can be used for almost any study. However, the null-hypothesis and hypothesis formats are stronger in their specificity and better define the relationship between two or more variables. Hypotheses are predictive statements. Null hypotheses can be thought of as a “no difference” contention or statement. Often hypotheses deal with probability. Null hypotheses deal with differences or change caused by some action or intervention. The choice of format can influence the approach to the problem as well as the statistical analysis of data collected.

All variables need to be identified as a study design is developed. Statistical analyses will determine the answers to the research questions, indicate whether null hypotheses should be retained or rejected, or prove the hypotheses. (See **BOX 3.2** for work practice.)

BOX 3.2 Revising a Topic from General to More Specific

Exercise: Consider the top choice problem (from Scenario 1). Work from general to specific in the manner outlined in the previous example.

Problem statement:

____

____

____

Question:

____

____

____

Aim/purpose:

____

____

____

Objective(s):

1. ______________________________
   ____
2. ______________________________
   ____
3. ______________________________
   ____
4. ______________________________
   ____
5. ______________________________
   ____
6. ______________________________
   ____
7. ______________________________
   ____

Scenario 2. A group of three students in a healthcare profession are required to identify a research problem and conduct a project as part of the curriculum. They choose to study the effectiveness of a new postoperative method for managing pain in surgical patients with herniated disks. They discuss the idea with their mentor, and they decide it is a worthwhile endeavor to determine whether the new method is "better" than the older methods. They discuss the following aspects of the study (suggested answers are given in parentheses):

- What information to gather (patient satisfaction, pain scales, etc.)
- Where to access the information (surgical practice)
- Whether to rely solely on subjective data (reported pain score) or to include objective data (type to be determined)
- What, if any, consents to obtain (patient and physician consent, approval from the IRB)
- Whether to recruit a consultant to help design the study or analyze the data after they are collected (perhaps a faculty member who is savvy in statistical methods)
- Whether the results should be published and in what medium (i.e., how the information should be disseminated)
- What the ethical issues are and how to address them (patient consent, confidentiality, etc.)
- Where to find financial support for the study (or could this be accomplished without incurring financial expenses?)

Research questions related to Scenario 2 include the following:

- How safe is the new method?
- What is the cost of the new method?
- What are the morbidity and mortality rates of the new method (compared to older methods)?
- What is the degree of patient satisfaction with the new method?
- How many work days (days for the patient return to normal activities) are saved using the new method (compared to established methods)?

As an exercise, the null hypothesis is used to develop the appropriate hypotheses:

- There are no differences in patient satisfaction between new and older methods.
- There are no differences in morbidity and mortality among patients undergoing the new vs. older methods of pain management.
- There are no differences in outcomes between the two methods.

Narrowing the Focus of the Question

To achieve the focus necessary, investigators must be systematic in the approach to honing and defining problems and questions. Generally, the research concept begins broad and becomes more specific.[2] Here is an example of one approach; an outline version is provided in **TABLE 3.2**.

Problem statement: There is no information on how many people, trained and educated as healthcare professionals, never practice clinically following successful completion of a program.

Question (problem converted into a question that can be answered): How many healthcare professionals do not practice clinically following successful completion of an educational program?

Aim (or purpose) of the research project: To determine how many students in healthcare professions do not practice clinically following successful completion of their particular program.

TABLE 3.2 Going from Broad to Specific

- Problem statement
- Question (problem converted into a question that can be answered)
- Aim/purpose
- Objective(s) (what the researcher(s) will do to answer the question)

Objective(s) (more specific than the aim): What the researcher is going to do to answer the question:

- Collect information on the number of graduates in healthcare professions who do not practice clinically
- Determine how many are males and how many are females
- Determine the age distribution of these graduates
- Determine how many practiced initially then stopped and how many never practiced
- Identify the reasons provided for not practicing clinically
- Determine whether the type of healthcare professional has any impact on the decision not to practice
- Determine the number of decisions based on personal, marital, financial, or other reasons

Here is a second (reverse) approach using a different problem. A group of public health nurses is interested in the subject of hyaline membrane disease, but they are not quite sure what to study and/or research. Moving from general to more specific, they take this approach:

1. Incidence of hyaline membrane disease (too broad)
2. Incidence of hyaline membrane disease in African American neonates (better)
3. Incidence of hyaline membrane disease in female African American neonates (even better)
4. Incidence of hyaline membrane disease in female African American neonates born to teen mothers (even more specific)
5. Incidence of hyaline membrane disease in female African American neonates born to teen mothers between 2010 and 2015 (getting even more specific)
6. Incidence of hyaline membrane disease in female African American neonates born to teen mothers between 2010 and 2015 in Hinds County, Mississippi (very specific)

The nurses have identified a research problem aimed at determining the incidence of hyaline membrane disease in a specific population. Is such a project feasible? Theoretically, yes it is; however, other issues have to be addressed and other factors must be considered, including costs and available resources, before the study can be performed successfully. As a cautionary point, if a study is too narrow in it subjects or demographics, there may be difficulty extrapolating findings to the general population. The final topic (number 6 in the previous list) is an example of a focus that may be too narrow.

Sources of Ideas for Research Problems

Some topics in the realm of possibility for any healthcare professional or student to research or, at least, explore for a research project include the following:

- The role of the healthcare professional in health promotion
- Learning styles of students in the healthcare professions
- Patient attitudes toward healthcare professionals
- Cost-effectiveness of healthcare professionals
- Best healthcare profession to provide a service
- Attitudes of healthcare professionals toward marginalized patient populations
- Impact of healthcare professionals on health care in medically underserved areas
- Any type of clinical investigation
- Does the professional degree level improve the quality of patient care? (Do higher degreed professionals provide better care?)
- Does research training in a program affect practice?
- The healthcare professional's niche in research
- Differences in professional healthcare practice by site (e.g., hospital, clinic, nursing home, etc.)
- The economic impact of a professional healthcare practice on a community
- Professional healthcare malpractice and liability
- What is the effect(s) of the Patient Protection and Affordable Care Act in areas such as access, delivery, demand, and the like?

Healthcare professionals, especially those new to research, may glean research ideas from various sources, including clinical practice (as in the scenario described earlier), literature review, interaction with other students in didactic and clinical settings, interactions with colleagues at meetings, interaction with supervisors, or published work where authors point out aspects that need to be explored further. Ideas can also be obtained from government, private, and public organizations (e.g., requests for proposals [RFPs] or funding opportunity announcements [FOAs]) that seek information and data on or about a particular subject or point of interest. These types of requests are distributed by government agencies or private foundations, and often are formulated by experts and specialty groups.[4]

Need for the Study

As alluded to previously, the need for studying a particular problem is determined by many factors such as the following:

- Significance in medical, legal, and socioeconomic terms[4]
- Whether the issue has already been addressed (i.e., its novelty)
- Acuity or seriousness
- Human, time, and financial costs
- Contribution to knowledge

A survey of nurse researchers indicated that focus on "real-world concerns" and soundness of methodology are the criteria of greatest significance in research projects, and that focus on timely or current concerns was less important.[4] On the other hand, personal interest in a particular problem may be the most important driving force.

Must a Study Be Original?

Although some researchers view replication studies as less scholarly and less valuable than original studies (an attitude that is more pervasive in some disciplines than in others), the fact remains that there are many instances where replication may be indicated, valuable, and needed. Some of the reasons studies are replicated include extending the generalizations of the findings, establishing credibility, reducing errors, and providing support for developing theories.[5] For novice researchers who might find identifying research topics and problems confusing and overwhelming, replication studies may be an excellent place to begin their first efforts.

Stating the Research Question

A good research question is one that can be answered using observable data or phenomena (something that can be observed and measured), includes the relationship between two or more variables, and is logical.[6] According to Sutherland et al.,[5] the three most frequently identified indices of the merit of a research question are potential impact, justification, and feasibility. These terms should be considered as research questions are developed. The questions should be posed straightforwardly, regardless of structure or format. Only one variable per research question should be addressed, if possible. Questions should be developed to explore the problem fully. One question answered well with sound methodology is better than many questions not answered well.

There are three ways to frame the research subject/question/project:

Null hypothesis: A statement of no relationship or difference between two variables. Example: There is no difference in outcomes between patients with acute otitis media treated with "watchful waiting" and those treated with antibiotics.

Hypothesis: A statement of prediction/observation that can be evaluated, measured, or analyzed. Example: Patients with acute otitis media treated with antibiotics have better outcomes than patients treated with "watchful waiting."

Research question: A question that needs to be answered through systematic testing/evaluation/analysis. Example: Is there a difference in outcomes between patients with acute otitis media treated with antibiotics versus watchful waiting?

Summary

The first step in any research effort is to identify the problem(s). Each problem is then put into a research question, hypothesis, or null-hypothesis format. These statements should be concise and should deal with only one variable or subject. Each statement must be in a form that allows investigation. In developing questions, a manageable number of questions or variables should be adopted. Small steps are best; some helpful tips are listed in **EXHIBIT 3.1**.

EXHIBIT 3.1 Pearls

1. Carry a pocket notebook or piece of paper and write down research ideas when they occur. Alternatively, use the notes app on your mobile phone.
2. Define the research problem in the most straightforward format.
3. Learn what is known or has been done about the problem or related issues.
4. Be able to define goals, objectives, and purposes.
5. Be able to describe the significance of research and why it can be the solution or part of the solution to the problem.
6. Be able to answer the question of why a project is important to society, health care, and your profession.

References

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CHAPTER 4

Review of the Literature

Laura Zeigen, MA, MLIS, MPH, AHIP

CHAPTER OVERVIEW

Before developing one's own research on a particular topic, a review of the existing published research related to that topic is essential. The review of existing research is commonly referred to as a "literature review." The findings of such a review are a necessary step for any researcher/writer in adequately framing and positioning their own research topic.

LEARNING OBJECTIVES

- Explain why literature reviews are important
- List the elements of a well-done literature review
- Identify the steps needed to conduct a literature review
- Determine appropriate databases and other searchable resources.
- Evaluate the sources/articles themselves and choose whether or not a particular resource will assist you in supporting the evidence needed for your argument

This chapter is designed as a guide through the systematic process of the literature review, including designing a research strategy, selecting the appropriate sources to search, performing effective and efficient searches, and critically analyzing search results. Note that a "systematic review" (as opposed to a "systematic process of the literature review") is its separate kind of specialized search.[1]

A well-done literature review should:

- Provide an overview of the existing research on the study topic
- "Map the territory" of the study topic: in which disciplines or broader areas of study does the question touch or overlap?
- Identify gaps in the literature (what is known and not known about this particular intersection of concepts)

- Identify core issues for this area of study. What aspects of this area of study have been well studied or under-studied? Which aspects appear to have consensus and which appear to continue to have differing opinions?
- Further clarify the "so what?" of how the researcher's question and work will contribute to filling the identified gap in existing research.

Introduction

Conducting research for a literature review falls within the larger conceptual framework of the five steps of evidence-based practice.[2] These five steps are outlined well in the Introduction to Evidence-Based Practice Tutorial from Duke University Medical Center Library (https://guides.mclibrary.duke.edu/ebmtutorial/home)[3] and are often conceptualized by different versions in **FIGURE 4.1**.

The first step in determining what has already been published on a topic is **ASK**. The ASK step involves developing a well-built, searchable question with which to approach the literature search. A searchable question is one that actually answers a question and is not so broad so as to be background information for a topic. For example, "cancer therapy" is too broad a topic to be manageable as a reasonable search one could conduct in a comprehensive way. What kind of cancer? In which part(s) of the body? At which stage? In which population of individuals? Treatment with which specific kind(s) of therapy? There are techniques discussed here and elsewhere that can help in developing a searchable question.[4]

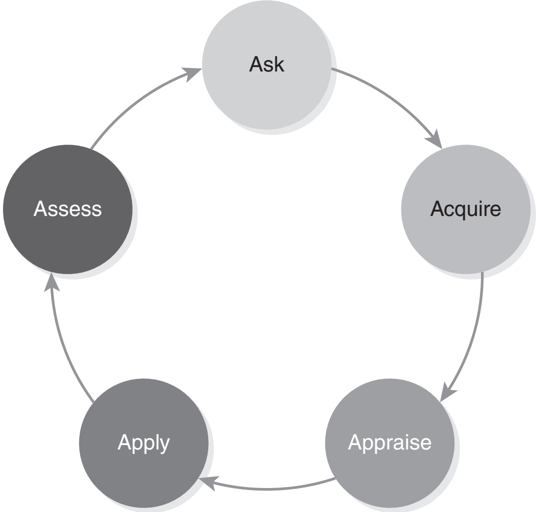


FIGURE 4.1 Using the medical literature to provide optimal patient care.

Based on 5 Steps of EBP – Introduction to Evidence-Based Practice Tutorial from Duke University Medical Center Library.

Some important considerations in the **ASK** phase include the following:

- After a searchable question is identified, figure out which disciplinary resources (peer-reviewed databases and websites and more) to consult. Most databases are subject/discipline specific.
- Use both primary (particularly peer-reviewed) and secondary sources (articles, websites or other resources that discuss primary research), as well as other types of sources like dissertation/theses.
- Other sources (like conference proceedings, reports from association websites and other "grey literature") that are not referenced in peer-reviewed databases are also useful.
- Some resources may be free, but many will be available to people associated with the institution through licensed databases.
- A single resource or database is ***never*** sufficient for a literature search.

Once a searchable question has been developed, searching for existing research related to various aspects of that question (the **ACQUIRE** phase) can be done. Searching appropriate disciplinary databases, as well as investigating relevant documents from resources such as governmental agencies, professional associations, non-profit organizations, funding institutions, conference proceedings, and dissertations, is necessary or conducting a truly comprehensive literature search. The literature search typically results in synthesis or summary of what is known on a particular topic, including strengths and weaknesses of existing research, where the researcher's question fits and how the researcher's work addresses a gap in existing research.

Some important considerations in the **ACQUIRE** phase include the following:

- Once databases are identified, look at the tutorials or help files for each database—time spent learning how to "talk" to the database (with either general or subject term/controlled vocabulary searches) will save time and frustration.
- Time spent consulting a librarian will save time and frustration later on.
- Utilize specific vocabulary (subject terms) for that database if one exists.
- Use "AND" and "OR" to find items that overlap on all aspects of the topic in question.
- Utilize "Pearl"-growing: in addition to looking "backwards" in time at a relevant article's reference list to see what sources that author used, utilize any institutional tools such as Web of Science or Scopus (or Google Scholar's "Cited by" feature) to look "forwards" in time and see which articles have cited the relevant article.
- PubMed and other databases sometimes have a "See similar articles" feature within a record that will bring up other related articles.
- Although the researcher may find a lot that appears useful, usually only a subset of citations found will be used.

The third step in the evidence-based practice process is **APPRAISE**. It is a good practice to appraise and evaluate the efficacy and strength of search results that come back from a particular search strategy. If one search strategy did not work well in providing expected literature results, a good researcher would try a variety of combinations of concepts and terms to determine which ones do work well.

How do you know if you have done a quality search? The "perfect" search does not exist. This "perfect" search would be if all articles on a topic are included in a single search query, and there are no non-relevant search results that appear in the search results. Searches, although they can never be perfect, can be improved. Time spent up front developing and executing well-thought out searches will mean less time and frustration in the future. The quality of a search can be evaluated using the following six metrics: sensitivity, specificity, precision, accuracy, number needed to read, and yield.[5] A novice searcher will have a higher "number needed to read" to synthesize the available information, and more experienced searchers will need to read less.

In the interest of saving time and frustration in the future, it is important for the researcher to document which searches ultimately worked well to answer certain parts of the searchable question. A writer can document the search with a Word® document, an online tool for tracking, a lab notebook, or something else. Along with this documentation, most databases offer the ability to save search strategies and save citations (similar to how many websites offer a "cart" in which one can see items that have been selected). To obtain access to these functions researchers may have to sign up for an account with that database, but there is usually no charge if the researcher has institutional access to that database. Accounts set up in PubMed, the free interface to the federally-funded National Library of Medicine database MEDLINE can be held on too long after a researcher leaves their particular institution (and, in fact, for life!). Most other, for-profit vendor driven databases will not offer such extended free access.

Once search strategies are appraised, the resulting studies themselves can be more thoroughly appraised and evaluated. Not everything that can be found, even in peer-reviewed databases, is of good quality, and even research studies of good quality by authoritative researchers on that topic can contain methodological or other limitations.[6]

Here are some questions to consider when appraising or evaluating which pieces of research to use:

- Are the authors experts in the field about which they write?
- Are the authors considered credible experts within an academic community?
- What potential biases might the authors have? For example, is their research on a particular drug funded by the company that produces that drug?
- When and where was the resource published?
- What type of article type is it?

- Did the work undergo a peer-review process before being published? Not all items even in peer-reviewed journals undergo peer review.

Articles published in professional journals can include original (primary) research such as cohort studies, clinical trial results, and results of large randomized studies. Journals may also include secondary information such as literature review (also called narrative review) articles on a single subject or comprehensive systematic reviews and meta-analyses, which try to identify, appraise, select, and carefully synthesize all high-quality research evidence relevant to a single question.

Peer review helps distinguish more authoritative research from articles that are opinion and lends credibility to the conclusions of the research described in those articles.[7]

There are different ways to tell if an article has been peer-reviewed. In some databases, such as CINAHL, there is a checkbox or other limiter that can be chosen with which to limit a result set to only peer-reviewed items. For databases that do not have that, check the article itself for items like the author's credentials (are they from an academic institution? Do they have a PhD in the field?), a methods section, and a listing that shows when the article was submitted, accepted or publication, and published. Another place to check is the journal website, which will often have a section geared toward authors explaining the peer-reviewed process if a journal engages in that process. Finally, if an institution has a subscription to Ulrich's (a database), this database can be searched by journal title. If the journal indicates, it is "refereed" it means it is a peer-reviewed journal. Again, however, even if a scholarly journal is considered a peer-reviewed journal, it does not mean that all articles within it are peer reviewed.

To obtain more information about and credibility of the authors of a research article, in addition to their listing of institution and credentials on a published article, more can be discerned about them through searching on them through a database such as Web of Science or Scopus. These databases make it easy to look up the larger body of publications of that author and verify their credentials, co-authors, and strength of their scholarly contributions to the field, sometimes known as h-index.[8]

Other considerations in the **APPRAISE** stage include the following:

- Sources should be carefully evaluated for relevance to the question under investigation.
- All sources cited should be thoroughly read and understood by the author before being included in a reference list.
- Sources should be accurately cited, so readers of the work understand the context in which the writer is referring to her ideas.

The APPLY and ASSESS aspects of the five steps of evidence-based practice fall outside the discussion on literature searching that inherently belong to the ASK, ACQUIRE, and APPRAISE stages and will not be discussed here.

ASK: The Details

It is important to carefully determine a study topic or research question as the first step in beginning the literature review. What information is needed? It may be useful to go through the process of creating a PICO table, VENN diagram, or mind map, or some other means of articulating the intersection of concepts the researcher is seeking to explore well before searching databases online.

PICO

PICO is a framework commonly utilized in clinical medicine to break down the concepts of a clinical question into keywords.[9,10,11] PICO is a mnemonic for this framework:

Remembering to include each of the PICO elements helps create a more specific, focused search. In this one above, a PICO applied into the MEDLINE database through PubMed might be executed both through a number of both keyword searches and subject terms that might look like this (**TABLE 4.1**):

PICO above as one possible keyword search:

women type 2 diabetes patient education a1c

TABLE 4.1 PICO

Element	Example
P = Patient or Population	Women over age 65 with Type 2 Diabetes Mellitus
I = Intervention or Exposure In clinical medicine, this is often the novel drug being tested (if a drug is being tested)	Patient education on management of disease
C = Comparison In clinical medicine, this is often the standard of care or standard medication. In areas outside clinical medicine (such as in public health or health services research) there often is no comparison element.	No patient education (sometimes there is no comparison)
O = Outcome The outcome can be as general as "health status" or as specific as a change in a certain biomarker.	Improved health status Hemoglobin A1C levels

PICO above as one possible subject term search:

("Diabetes Mellitus, Type 2/prevention and control" [Mesh] AND "Patient Education as Topic" [Mesh] AND "Glycated Hemoglobin A" [Mesh])

Subject term searching in PubMed and other databases is discussed in detail further on.

VENN Diagram

A VENN diagram is just a simple bubble diagram that is a visual representation of the elements of the search. Drawing one out can be a helpful reminder for including all PICO elements and also can be a reminder that the search is not about finding all articles on one topic (here, Type 2 Diabetes Mellitus), but the INTERSECTION of that topic with one or more other topics (the center of the circle where the topics overlap). Having a VENN diagram (**FIGURE 4.2**) can help when to AND and OR different elements of the search:

AND = Used to create an intersection. The search results MUST contain both or all elements "AND"-ed together

OR = Used to create a larger "concept pile." The search results MAY contain (but are not required to contain) one or more of the concepts. The operator OR usually happens with concepts that are more or less synonyms and go in the same PICO element.

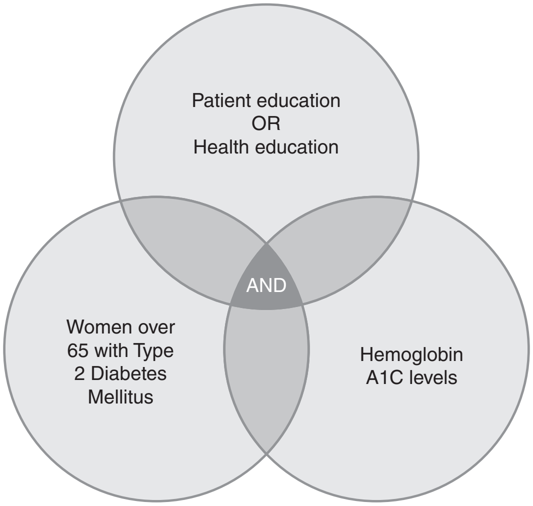


FIGURE 4.2 VENN Diagram showing intersection of PICO elements.

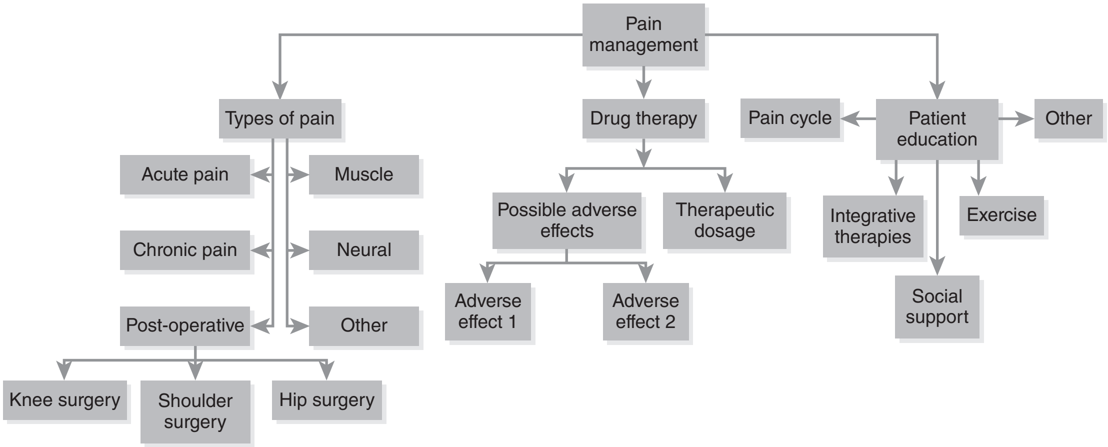

Pain management
Types of pain
Acute pain
Muscle
Chronic pain
Neural
Post-operative
Other
Knee surgery
Shoulder surgery
Hip surgery
Drug therapy
Possible adverse effects
Therapeutic dosage
Adverse effect 1
Adverse effect 2
Pain cycle
Patient education
Other
Integrative therapies
Exercise
Social support

FIGURE 4.3 Mind map of PICO elements.

Mind Map

Mind maps are diagrams used to represent information visually and have been shown to assist in people's understanding of complex relationships between concepts.[12] In a way, a VENN diagram could be seen as an extremely simplistic mind map. One way to construct mind maps is to write out the central idea in the middle of a page, then write down all connecting idea to that central concept in a tree/branch-like structure to show relationships between these concepts. See **FIGURE 4.3**, software exists to create mind maps (or the related concepts maps), but often mind maps are created by hand.

Taking the time to develop a well-written, carefully defined, and focused research question helps the researcher choose the best resources for the literature search and the most appropriate keywords and subject terms to use during the search process. Because the results are more precise, a focused research question avoids wasting time as the search is performed and allows the researcher to more readily recognize when results are or are not relevant.

For example, a research interest may involve the role of patient compliance (also known as patient adherence) on treatment outcome. What specifically about patient compliance and treatment outcome are of interest? What are the barriers to or supporting factors of patient compliance? What is the role of health personnel in impacting patient compliance? What are current best practices in supporting patient compliance? What can the economic impact of patient adherence be on the patient and the healthcare system? The more specific the topic of inquiry, the better the resulting review will be. Health sciences librarians can assist with the development of these searchable research questions.

ACQUIRE: The Details

Database Searching

Databases can be searched in a variety of ways, but there are usually two primary ways of searching most databases: keyword searching and subject heading searching.

Keyword searching could be referred to as "regular" searching, or the searching most people have become accustomed to in Google or Amazon.com; that of putting a bunch of words in the available database search box and searching. Each database will treat this kind of search slightly differently, but often the system will search for the existence of each of the terms entered. This usually brings back at least some results that have all these words contained in some way in the resulting citations. However, just because the search words appear in a resulting citation does not necessarily mean that the citation or article is actually about that particular topic.

Subject searching, the other primary kind of searching, ensures that the citations returned in a search result set are actually about the topic or topics that have been searched. In these searches, terms from a controlled vocabulary for that discipline are used.

If searches using the controlled vocabulary do not provide a satisfactory result or if there is no controlled vocabulary for the database being searched, searching by author, journal title, publication type, research type, questionnaire, and many other indexed fields of the record can also be productive. Available fields vary among databases.

The best approach to searching for subject terms is to search for each term separately and then to combine them. In this way, subject term searching is similar to baking, where each ingredient is first taken out of the cupboard and put on the counter before ingredients are mixed together in a deliberate order. "Regular"/"Google"-like searching (without using the subject terms) is more akin to throwing a bunch of ingredients into a crockpot to make a stew. These are two different searching processes ("regular"/keyword searching and subject term searching) and searching is most effective when both types are utilized. Subjects can be combined with an author's name; an author's name can be combined with a journal title; a word or phrase search can be combined with a questionnaire name, and so on. In most databases, at least two options for combining sets are available: OR or AND. When using OR, the retrieval from two (or more) sets is pooled. Thus, the number of retrieved items is larger than any of the individual sets. When using AND, the combined set containing each individual item must be present. Thus, the number of retrieved items is smaller than any of the individual sets. Any number of search terms can be combined, but when using AND, the more items that are combined, the smaller the number of items retrieved. The OR and AND operators are often illustrated using Venn diagrams as shown in Figure 4.2. A general search flow in any given database might look something like this:

Steps in the literature review process also in FIGURE 4.4:

1. Develop searchable question (PICO/VENN/Mind Map)
2. Determine which databases/resources to use
3. Search help files/tutorials/videos to learn what syntax rules apply in that database and/or meet with a librarian

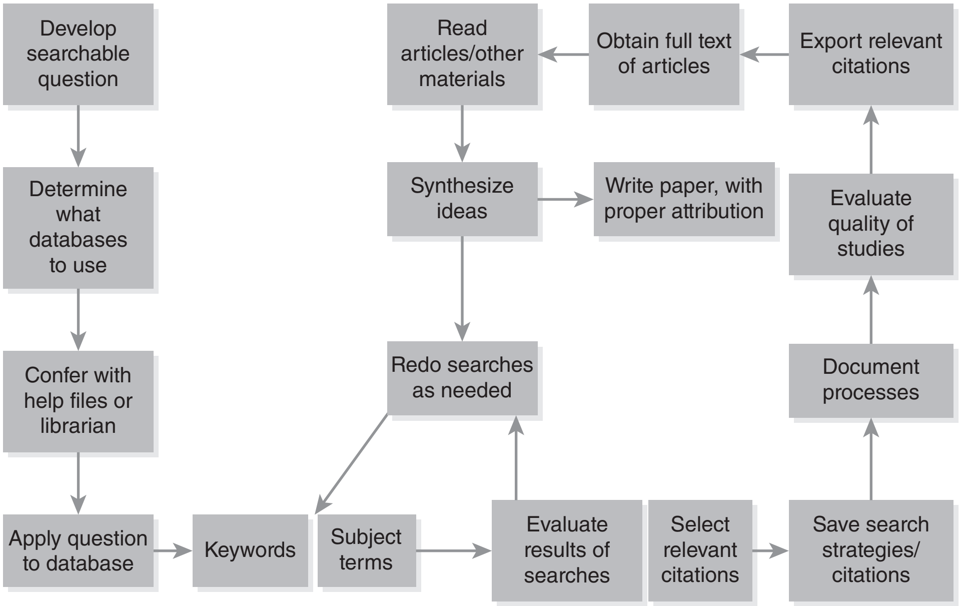

Develop searchable question
Determine what databases to use
Confer with help files or librarian
Apply question to database
Keywords
Subject terms
Evaluate results of searches
Select relevant citations
Save search strategies/ citations
Document processes
Evaluate quality of studies
Export relevant citations
Obtain full text of articles
Read articles/other materials
Synthesize ideas
Write paper, with proper attribution
Redo searches as needed

FIGURE 4.4 Steps in the literature search process.

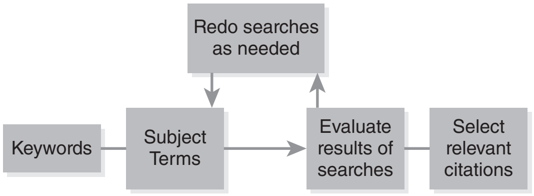


FIGURE 4.5 Process of evaluating search results and reworking searches as needed.

4. Apply searchable question into the database: general search.
5. Apply searchable question into the database: subject term search.
6. Evaluate search results
7. Redo search as needed (see **FIGURE 4.5**).
8. Choose relevant citations as found from each search along the way
9. Save search strategies and/or citations through the database.
10. Document the process ("lab notebook").
11. Evaluate the quality of the studies chosen; if not adequate, do not use.
12. Export citations found to be useful/relevant/authoritative.
13. Obtain full text of articles via citation software or through links in the database to the institutional subscriptions.
14. Synthesize ideas from articles read and other materials consulted.
15. Write the research paper, making sure to include proper attributions and correct citations.

A specific example showing the application of going through these steps, specifically the search, evaluation of the search, and redoing of the search, as applied to the PubMed/MEDLINE database, is in Figures 5–25. *Example: What are effective drug therapies that can be used to alleviate the symptoms of psoriasis in adolescents?*

Specific Databases

Each database works slightly differently and, due to the respective disciplinary knowledge represented by that database, will contain a slightly, or more than slightly, different "inventory" of articles than other databases. Briefly checking the "Help" files or FAQ for a particular database before diving in to apply the searchable question to that database can help the researcher be more efficient and save time. Although librarians are database learning resources, they often ask the researcher what searches have been tried previously.

MEDLINE

MEDLINE, developed and hosted by the National Library of Medicine, is the largest health and science database in North America and includes indexed journal article citations dating back to 1948 (https://www.nlm.nih.gov/bsd/medline.html). MEDLINE provides links to biomedical information in professional journals in the subject areas of medicine, dentistry, nursing, allied health, veterinary medicine, and the biomedical sciences. MEDLINE is free to all and is part of the content provided by of a user-friendly interface called PubMed (http://pubmed.gov). Many academic institutions set up access to PubMed in a way that enables seamless linking to full-text articles subscribed to by the institution and they may also buy access to MEDLINE through proprietary interfaces like Ovid or the Elton B. Stephens Company (EBSCO). As MEDLINE is a freely available database through Pubmed, screenshots showing certain MEDLINE/PubMed searching are included in accompanying slides. Additionally, PubMed has some online tutorials (https://learn.nlm.nih.gov/documentation/training-packets/T0042010P/) and YouTube videos which can be referenced to learn more.

Most disciplinary-specific databases utilize something called a controlled vocabulary, or "established list of standardized terminology for use in indexing and retrieval of information." (https://stats.oecd.org/glossary/detail.asp?ID=6260). Controlled vocabulary terms (often called *subject terms*) are added as part of the citation record before the record is added to the database. Assigning controlled vocabulary terms is a way of uniformly indexing articles by subject. Utilizing a controlled vocabulary eliminates synonyms or other issues of natural language. The controlled vocabulary used in MEDLINE is called

MeSH (Medical Subject Headings). Sometimes the MeSH terms are the same as the keywords for a particular concept: the keyword *psoriasis* has the same MeSH term *psoriasis*. Sometimes, however, the MeSH terms are different: the keyword phrase *breast cancer, for example,* maps to the MeSH term *breast neoplasms*. Additional examples are working with MeSH are available in slides 7–30.

MeSH terms can be combined with AND or OR within PubMed's "Advanced Search" to achieve precise results. More information about using MeSH is available at https://www.nlm.nih.gov/mesh/ and https://www.nlm.nih.gov/mesh/intro_preface.html#pref_rem. Limits or filters, such as the dates of publication or limiting to a particular age group or publication type can be utilized to refine search results further.

Searching MEDLINE through PubMed yields some citations that link to the full text of articles available for free or via "open access." Free and open-access articles are selected from a range of journals and are deposited there by publishers for free access. A separate database called PubMed Central (PMC) also freely offers the author-prepared manuscripts of articles (not the final published versions) by authors whose research was funded by the National Institutes of Health. PMC can be searched directly at http://pubmedcentral.gov. Note that the author's manuscript can sometimes differ from the final published version. An open access publisher called Biomed Central (http://www.biomedcentral.com) provides access to over 250 peer-reviewed open access journals in science, technology, and medicine. Articles in these journals are linked through their citations in PubMed. Other than the journal articles available through PubMed, PubMed Central, and Biomed Central, access to articles published in most professional journals is not free. An academic library that subscribes to various journals can provide access to them, or articles may be ordered through an institutional library's interlibrary loan service.

An example of how it would look to do keyword and subject term (controlled vocabulary) searching in MEDLINE using the PubMed interface is shown in Figures 4.7–4.25 slides 10–29 and described below. In this example, the search is on psoriasis, specifically on drug therapy and preventive treatment, specifically looking at this condition in adolescents. The PICO and VENN for this specific example are in **TABLE 4.2** and in **FIGURE 4.6**.

TABLE 4.2 MEDLINE PICO

Element	Example
P = Patient or Population	Adolescents with psoriasis
I = Intervention or Exposure In clinical medicine, this is often the novel drug being tested (if a drug is being tested)	Drug therapies
C = Comparison In clinical medicine, this is often the standard of care or standard medication. In areas outside clinical medicine (such as in public health or health services research) there often is no comparison element.	No drug therapy
O = Outcome This outcome can be as general as "health status" or as specific as a change in a certain biomarker.	Improved health status Lessening to symptoms

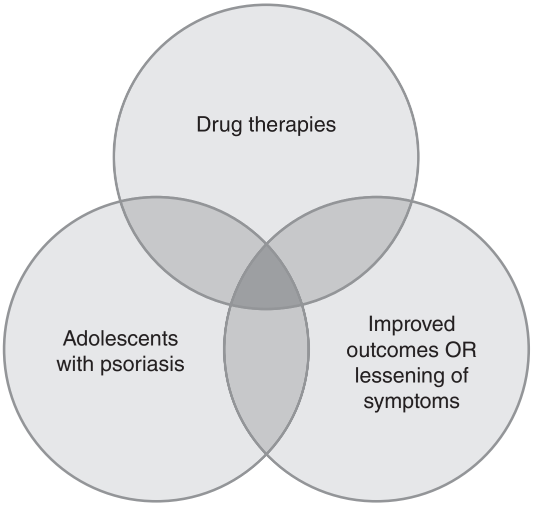
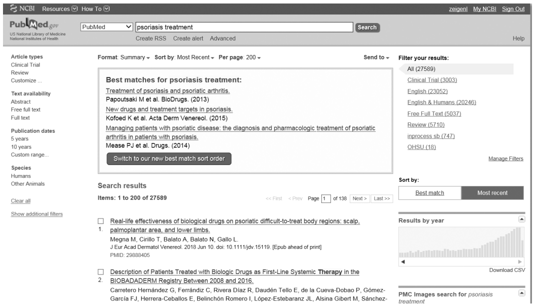

Drug therapies
Adolescents with psoriasis
Improved outcomes OR lessening of symptoms

FIGURE 4.6 Our example question shown as a VENN Diagram, showing intersection of PICO elements.

Example of keyword and subject terms search cycle.

1. A keyword search on **psoriasis treatment** yields over 27,000 articles (see **FIGURE 4.7**).
    - Starting with a general keyword search in PubMed is a great way to start exploring a topic, but the number of citations from such a search is often unmanageable, and the list likely contains many citations that are not relevant to the researcher's specific question. This kind of search is overly broad and needs to be narrowed.


NCBI
Resources
How To
zeigenl
My NCBI
Sign Out
PubMed.gov
US National Library of Medicine
National Institutes of Health
PubMed
Search
Create RSS
Create alert
Advanced
Help
Article types
Clinical Trial
Review
Customize ...
Text availability
Abstract
Free full text
Full text
Publication dates
5 years
10 years
Custom range...
Species
Humans
Other Animals
Clear all
Show additional filters
Format: Summary
Sort by: Most Recent
Per page: 200
Send to
Filter your results:
All (27589)
Clinical Trial (3003)
English (23052)
English & Humans (20246)
Free Full Text (5037)
Review (5710)
inprocess sb (747)
OHSU (18)
Manage Filters
Switch to our new best match sort order
Sort by:
Best match
Most recent
<< First
< Prev
Page
of 138
Next >
Last >>
Results by year
Download CSV
PMC Images search for *psoriasis treatment*

psoriasis treatment

Best matches for psoriasis treatment:

Treatment of psoriasis and psoriatic arthritis.
Papoutsaki M et al. BioDrugs. (2013)

New drugs and treatment targets in psoriasis.
Kofoed K et al. Acta Derm Venereol. (2015)

Managing patients with psoriatic disease: the diagnosis and pharmacologic treatment of psoriatic arthritis in patients with psoriasis.
Mease PJ et al. Drugs. (2014)

Search results

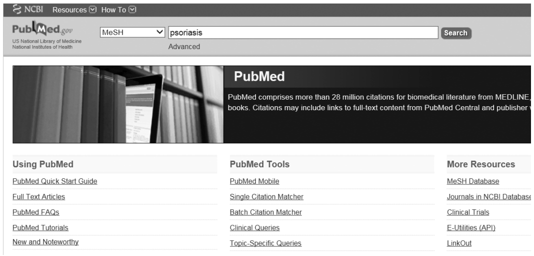
Items: 1 to 200 of 27589

☐ 1. Real-life effectiveness of biological drugs on psoriatic difficult-to-treat body regions: scalp, palmoplantar area, and lower limbs.
Megna M, Cirillo T, Balato A, Balato N, Gallo L.
J Eur Acad Dermatol Venereol. 2018 Jun 10. doi: 10.1111/jdv.15119. [Epub ahead of print]
PMID: 29888405

☐ 2. Description of Patients Treated with Biologic Drugs as First-Line Systemic **Therapy** in the BIOBADADERM Registry Between 2008 and 2016.
Carretero Hernández G, Ferrándiz C, Rivera Díaz R, Daudén Tello E, de la Cueva-Dobao P, Gómez-García FJ, Herrera-Ceballos E, Belinchón Romero I, López-Estebaranz JL, Alsina Gibert M, Sánchez-

FIGURE 4.7 Results of a keyword search.

Courtesy of National Center for Biotechnology Information.


NCBI
Resources
How To
PubMed.gov
US National Library of Medicine
National Institutes of Health
MeSH
Search
Advanced
PubMed
Using PubMed
PubMed Quick Start Guide
Full Text Articles
PubMed FAQs
PubMed Tutorials
New and Noteworthy
PubMed Tools
PubMed Mobile
Single Citation Matcher
Batch Citation Matcher
Clinical Queries
Topic-Specific Queries
More Resources
MeSH Database
Journals in NCBI Database
Clinical Trials
E-Utilities (API)
LinkOut

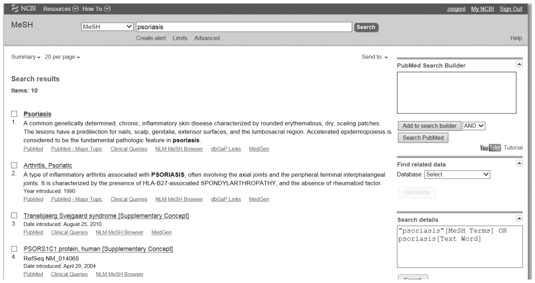
psoriasis

PubMed comprises more than 28 million citations for biomedical literature from MEDLINE, books. Citations may include links to full-text content from PubMed Central and publisher

FIGURE 4.8 Starting a MeSH search.

Courtesy of National Center for Biotechnology Information.

2. Click on the drop-down menu at the top of the PubMed page and choose "MeSH" before putting in the search term and clicking "Search" (see **FIGURE 4.8**).
    - Using the MeSH-controlled vocabulary within PubMed helps refine results.
3. A list of MeSH terms related to the MeSH term search **psoriasis** comes up (see **FIGURE 4.9**).
4. Clicking on the first link brings up the MeSH record for that concept as shown in **FIGURE 4.10**.
    - Scrolling down within a MeSH record can reveal valuable additional information, including where that MeSH concept resides in the entire MeSH hierarchy.
    - To add that MeSH term to the list of terms available to search further, click on the **Add to Search Builder (BUILDER)** button in the upper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Search
Create alert
Limits
Advanced
Help
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20 per page
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PubMed Search Builder
Add to search builder
AND
Search PubMed
YouTube Tutorial
Find related data
Database:
Select
Find items
Search details
Search
PubMed
PubMed - Major Topic
Clinical Queries
NLM MeSH Browser
dbGaP Links
MedGen

psoriasis

Search results

Items: 10

☐ 1. Psoriasis
A common genetically determined, chronic, inflammatory skin disease characterized by rounded erythematous, dry, scaling patches. The lesions have a predilection for nails, scalp, genitalia, extensor surfaces, and the lumbosacral region. Accelerated epidermopoiesis is considered to be the fundamental pathologic feature in **psoriasis**.

☐ 2. Arthritis, Psoriatic
A type of inflammatory arthritis associated with **PSORIASIS**, often involving the axial joints and the peripheral terminal interphalangeal joints. It is characterized by the presence of HLA-B27-associated SPONDYLARTHROPATHY, and the absence of rheumatoid factor.
Year introduced: 1990

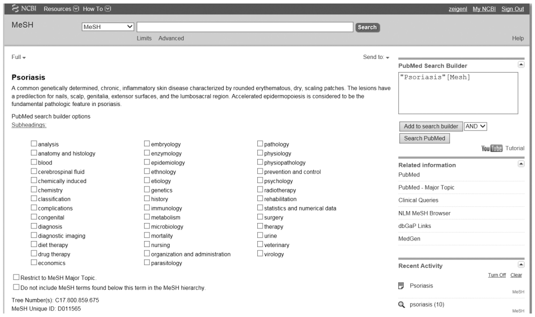
☐ 3. Tranebjaerg Svejgaard syndrome [Supplementary Concept]
Date introduced: August 25, 2010

☐ 4. PSORS1C1 protein, human [Supplementary Concept]
RefSeq NM_014068
Date introduced: April 29, 2004

```
"psoriasis"[MeSH Terms] OR
psoriasis[Text Word]
```

FIGURE 4.9 Results from searching on a particular MeSH term.

Courtesy of National Center for Biotechnology Information.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Sign Out
MeSH
MeSH
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Limits
Advanced
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Full
Send to:
PubMed Search Builder
Add to search builder
AND
Search PubMed
YouTube Tutorial
Related information
PubMed
PubMed - Major Topic
Clinical Queries
NLM MeSH Browser
dbGaP Links
MedGen
Recent Activity
Turn Off
Clear
Psoriasis
MeSH
psoriasis (10)
MeSH
☐ analysis
☐ anatomy and histology
☐ blood
☐ cerebrospinal fluid
☐ chemically induced
☐ chemistry
☐ classification
☐ complications
☐ congenital
☐ diagnosis
☐ diagnostic imaging
☐ diet therapy
☐ drug therapy
☐ economics
☐ embryology
☐ enzymology
☐ epidemiology
☐ ethnology
☐ etiology
☐ genetics
☐ history
☐ immunology
☐ metabolism
☐ microbiology
☐ mortality
☐ nursing
☐ organization and administration
☐ parasitology
☐ pathology
☐ physiology
☐ physiopathology
☐ prevention and control
☐ psychology
☐ radiotherapy
☐ rehabilitation
☐ statistics and numerical data
☐ surgery
☐ therapy
☐ urine
☐ veterinary
☐ virology

"Psoriasis"[Mesh]

Psoriasis

A common genetically determined, chronic, inflammatory skin disease characterized by rounded erythematous, dry, scaling patches. The lesions have a predilection for nails, scalp, genitalia, extensor surfaces, and the lumbosacral region. Accelerated epidermopoiesis is considered to be the fundamental pathologic feature in psoriasis.

PubMed search builder options
Subheadings:

☐ Restrict to MeSH Major Topic.
☐ Do not include MeSH terms found below this term in the MeSH hierarchy.

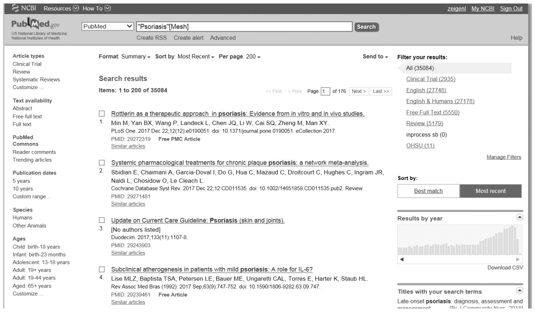
Tree Number(s): C17.800.859.675
MeSH Unique ID: D011565

FIGURE 4.10 A MeSH record.

Courtesy of National Center for Biotechnology Information.

right (this adds the MeSH syntax to the box), then the **Search PubMed** button, which executes the search in PubMed.

5. All articles having that chosen MeSH term assigned are displayed in **FIGURE 4.11**.
6. Repeat steps 2-5 for each MeSH term, here **drug therapy** (see **FIGURES 4.12–4.14**).
7. Click on the **Advanced Search** link under the search box to get to the Advanced Search function.
   - Advanced Search is where the most recent search history can be found
   - Advanced Search is where "AND"-ing and "OR"-ing can take place (see **FIGURE 4.15**).


NCBI
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PubMed.gov
US National Library of Medicine
National Institutes of Health
PubMed
Search
Create RSS
Create alert
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Help
Article types
Clinical Trial
Review
Systematic Reviews
Customize ...
Text availability
Abstract
Free full text
Full text
PubMed Commons
Reader comments
Trending articles
Publication dates
5 years
10 years
Custom range...
Species
Humans
Other Animals
Ages
Child: birth-18 years
Infant: birth-23 months
Adolescent: 13-18 years
Adult: 19+ years
Adult: 19-44 years
Aged: 65+ years
Customize ...
Format: Summary
Sort by: Most Recent
Per page: 200
Send to
<< First
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Next >
Last >>
Filter your results:
All (35084)
Clinical Trial (2935)
English (27748)
English & Humans (27178)
Free Full Text (5550)
Review (5179)
inprocess sb (0)
OHSU (11)
Manage Filters
Sort by:
Best match
Most recent
Results by year
Download CSV
Titles with your search terms

"Psoriasis"[Mesh]

Search results

Items: 1 to 200 of 35084

Page 1 of 176

1. Rottlerin as a therapeutic approach in **psoriasis**: Evidence from in vitro and in vivo studies.
Min M, Yan BX, Wang P, Landeck L, Chen JQ, Li W, Cai SQ, Zheng M, Man XY.
PLoS One. 2017 Dec 22;12(12):e0190051. doi: 10.1371/journal.pone.0190051. eCollection 2017.
PMID: 29272319 **Free PMC Article**
Similar articles

2. Systemic pharmacological treatments for chronic plaque **psoriasis**: a network meta-analysis.
Sbidian E, Chaimani A, Garcia-Doval I, Do G, Hua C, Mazaud C, Droitcourt C, Hughes C, Ingram JR, Naldi L, Chosidow O, Le Cleach L.
Cochrane Database Syst Rev. 2017 Dec 22;12:CD011535. doi: 10.1002/14651858.CD011535.pub2. Review.
PMID: 29271481
Similar articles

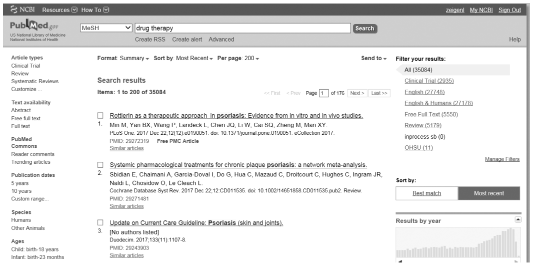
3. Update on Current Care Guideline: **Psoriasis** (skin and joints).
[No authors listed]
Duodecim. 2017;133(11):1107-8.
PMID: 29243903
Similar articles

4. Subclinical atherogenesis in patients with mild **psoriasis**: A role for IL-6?
Lise MLZ, Baptista TSA, Petersen LE, Bauer ME, Ungaretti CAL, Torres E, Harter K, Staub HL.
Rev Assoc Med Bras (1992). 2017 Sep;63(9):747-752. doi: 10.1590/1806-9282.63.09.747.
PMID: 29239461 **Free Article**
Similar articles

Late-onset **psoriasis**: diagnosis, assessment and

FIGURE 4.11 Results from a search on a MeSH term.

Courtesy of National Center for Biotechnology Information.


NCBI
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My NCBI
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PubMed.gov
US National Library of Medicine
National Institutes of Health
MeSH
Search
Create RSS
Create alert
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Article types
Clinical Trial
Review
Systematic Reviews
Customize ...
Text availability
Abstract
Free full text
Full text
PubMed Commons
Reader comments
Trending articles
Publication dates
5 years
10 years
Custom range...
Species
Humans
Other Animals
Ages
Child: birth-18 years
Infant: birth-23 months
Format: Summary
Sort by: Most Recent
Per page: 200
Send to
<< First
< Prev
Next >
Last >>
Filter your results:
All (35084)
Clinical Trial (2935)
English (27748)
English & Humans (27178)
Free Full Text (5550)
Review (5179)
inprocess sb (0)
OHSU (11)
Manage Filters
Sort by:
Best match
Most recent
Results by year

drug therapy

Search results

Items: 1 to 200 of 35084

Page 1 of 176

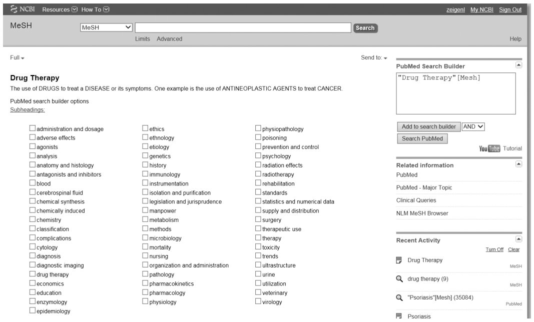
1. Rottlerin as a therapeutic approach in **psoriasis**: Evidence from in vitro and in vivo studies.
Min M, Yan BX, Wang P, Landeck L, Chen JQ, Li W, Cai SQ, Zheng M, Man XY.
PLoS One. 2017 Dec 22;12(12):e0190051. doi: 10.1371/journal.pone.0190051. eCollection 2017.
PMID: 29272319 **Free PMC Article**
Similar articles

2. Systemic pharmacological treatments for chronic plaque **psoriasis**: a network meta-analysis.
Sbidian E, Chaimani A, Garcia-Doval I, Do G, Hua C, Mazaud C, Droitcourt C, Hughes C, Ingram JR, Naldi L, Chosidow O, Le Cleach L.
Cochrane Database Syst Rev. 2017 Dec 22;12:CD011535. doi: 10.1002/14651858.CD011535.pub2. Review.
PMID: 29271481
Similar articles

3. Update on Current Care Guideline: **Psoriasis** (skin and joints).
[No authors listed]
Duodecim. 2017;133(11):1107-8.
PMID: 29243903
Similar articles

FIGURE 4.12 MeSH search on second MeSH term.

Courtesy of National Center for Biotechnology Information.


NCBI
Resources
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My NCBI
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MeSH
MeSH
Search
Limits
Advanced
Help
Full
Send to:
PubMed Search Builder
Add to search builder
AND
Search PubMed
YouTube Tutorial
Related information
PubMed
PubMed - Major Topic
Clinical Queries
NLM MeSH Browser
Recent Activity
Turn Off
Clear
Drug Therapy
MeSH
drug therapy (9)
MeSH
"Psoriasis"[Mesh] (35084)
PubMed
Psoriasis
☐ administration and dosage
☐ adverse effects
☐ agonists
☐ analysis
☐ anatomy and histology
☐ antagonists and inhibitors
☐ blood
☐ cerebrospinal fluid
☐ chemical synthesis
☐ chemically induced
☐ chemistry
☐ classification
☐ complications
☐ cytology
☐ diagnosis
☐ diagnostic imaging
☐ drug therapy
☐ economics
☐ education
☐ enzymology
☐ epidemiology
☐ ethics
☐ ethnology
☐ etiology
☐ genetics
☐ history
☐ immunology
☐ instrumentation
☐ isolation and purification
☐ legislation and jurisprudence
☐ manpower
☐ metabolism
☐ methods
☐ microbiology
☐ mortality
☐ nursing
☐ organization and administration
☐ pathology
☐ pharmacokinetics
☐ pharmacology
☐ physiology
☐ physiopathology
☐ poisoning
☐ prevention and control
☐ psychology
☐ radiation effects
☐ radiotherapy
☐ rehabilitation
☐ standards
☐ statistics and numerical data
☐ supply and distribution
☐ surgery
☐ therapeutic use
☐ therapy
☐ toxicity
☐ trends
☐ ultrastructure
☐ urine
☐ utilization
☐ veterinary
☐ virology

"Drug Therapy"[Mesh]

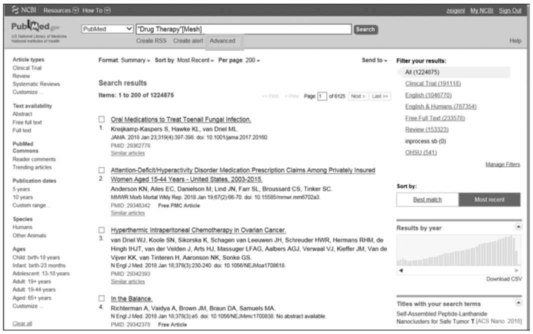
Drug Therapy

The use of DRUGS to treat a DISEASE or its symptoms. One example is the use of ANTINEOPLASTIC AGENTS to treat CANCER.

PubMed search builder options
Subheadings:

FIGURE 4.13 MeSH record for one of the search terms.

Courtesy of National Center for Biotechnology Information.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PubMed.gov
US National Library of Medicine
National Institutes of Health
PubMed
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Create RSS
Create alert
Advanced
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Article types
Clinical Trial
Review
Systematic Reviews
Customize ...
Text availability
Abstract
Free full text
Full text
PubMed Commons
Reader comments
Trending articles
Publication dates
5 years
10 years
Custom range...
Species
Humans
Other Animals
Ages
Child: birth-18 years
Infant: birth-23 months
Adolescent: 13-18 years
Adult: 19+ years
Adult: 19-44 years
Aged: 65+ years
Customize ...
Clear all
Format: Summary
Sort by: Most Recent
Per page: 200
Send to
<< First
< Prev
Next >
Last >>
Filter your results:
All (1224875)
Clinical Trial (191118)
English (1046770)
English & Humans (787354)
Free Full Text (233578)
Review (153323)
inprocess sb (0)
OHSU (541)
Manage Filters
Sort by:
Best match
Most recent
Results by year
Download CSV
Titles with your search terms

"Drug Therapy"[Mesh]

Search results

Items: 1 to 200 of 1224875

Page 1 of 6125

1. Oral Medications to Treat Toenail Fungal Infection.
Kreijkamp-Kaspers S, Hawke KL, van Driel ML.
JAMA. 2018 Jan 23;319(4):397-398. doi: 10.1001/jama.2017.20160.
PMID: 29362778
Similar articles

2. Attention-Deficit/Hyperactivity Disorder Medication Prescription Claims Among Privately Insured Women Aged 15-44 Years - United States, 2003-2015.
Anderson KN, Ailes EC, Danielson M, Lind JN, Farr SL, Broussard CS, Tinker SC.
MMWR Morb Mortal Wkly Rep. 2018 Jan 19;67(2):66-70. doi: 10.15585/mmwr.mm6702a3.
PMID: 29346342 **Free PMC Article**
Similar articles

3. Hyperthermic Intraperitoneal Chemotherapy in Ovarian Cancer.
van Driel WJ, Koole SN, Sikorska K, Schagen van Leeuwen JH, Schreuder HWR, Hermans RHM, de Hingh IHJT, van der Velden J, Arts HJ, Massuger LFAG, Aalbers AGJ, Verwaal VJ, Kieffer JM, Van de Vijver KK, van Tinteren H, Aaronson NK, Sonke GS.
N Engl J Med. 2018 Jan 18;378(3):230-240. doi: 10.1056/NEJMoa1708618.
PMID: 29342393
Similar articles

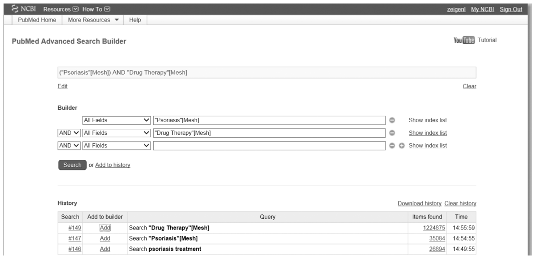
4. In the Balance.
Richterman A, Vaidya A, Brown JM, Braun DA, Samuels MA.
N Engl J Med. 2018 Jan 18;378(3):e5. doi: 10.1056/NEJMimc1700838. No abstract available.
PMID: 29342378 **Free Article**

Self-Assembled Peptide-Lanthanide Nanoclusters for Safe Tumor **T** [ACS Nano. 2018]

FIGURE 4.14 Results for search on one of the MeSH terms.

Courtesy of National Center for Biotechnology Information.

8. Click on the **Add** links for desired elements in the search.
   - This step will populate the search boxes above.
   - The default connector is AND, but this can be changed to OR if needed.



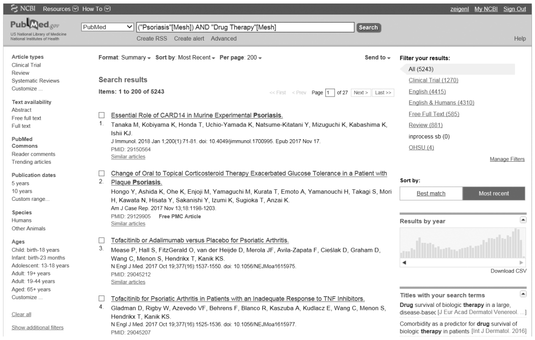
PubMed Advanced Search Builder

("Psoriasis"[Mesh]) AND "Drug Therapy"[Mesh]

FIGURE 4.15 Advanced Search.

Courtesy of National Center for Biotechnology Information.

9. The resulting search (**FIGURE 4.16**) shows all articles in MEDLINE assigned both of the MeSH terms searched. Further refinements to this search can be applied.
10. To limit the search results set to review articles, click the **Review** link under **Article Types** in the left-hand navigation as shown in **FIGURE 4.17**.
    - Additional Article Types may be brought up by clicking the **Customize** link (**FIGURE 4.18**) and clicking the checkboxes of the options desired.



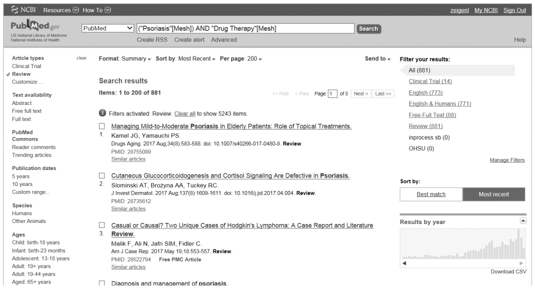
("Psoriasis"[Mesh]) AND "Drug Therapy"[Mesh]

Search results

Items: 1 to 200 of 5243

FIGURE 4.16 Results of a search combining two MeSH terms.

Courtesy of National Center for Biotechnology Information.



("Psoriasis"[Mesh]) AND "Drug Therapy"[Mesh]

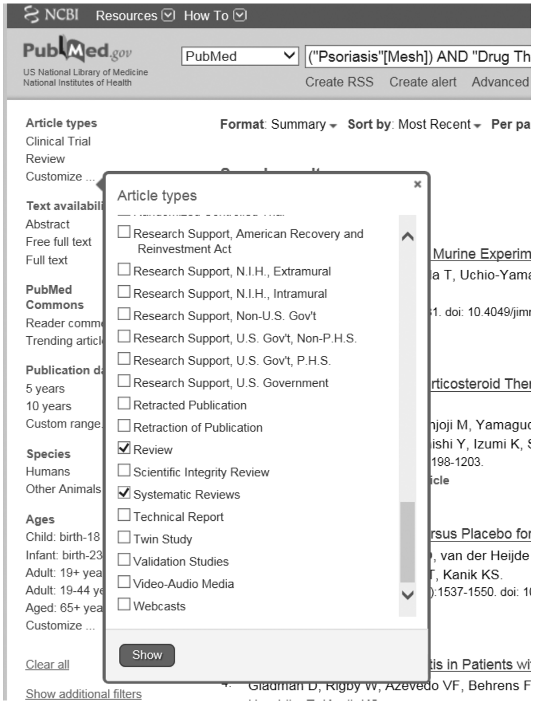
Search results

Items: 1 to 200 of 881

Filters activated: Review. Clear all to show 5243 items.

FIGURE 4.17 Limits and Filters.

Courtesy of National Center for Biotechnology Information.



("Psoriasis"[Mesh]) AND "Drug Th

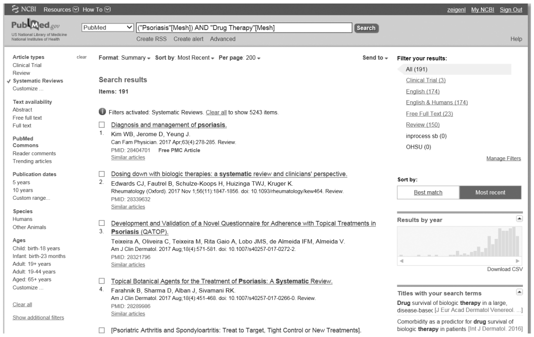
Article types

☐ Research Support, American Recovery and Reinvestment Act
☐ Research Support, N.I.H., Extramural
☐ Research Support, N.I.H., Intramural
☐ Research Support, Non-U.S. Gov't
☐ Research Support, U.S. Gov't, Non-P.H.S.
☐ Research Support, U.S. Gov't, P.H.S.
☐ Research Support, U.S. Government
☐ Retracted Publication
☐ Retraction of Publication
☑ Review
☐ Scientific Integrity Review
☑ Systematic Reviews
☐ Technical Report
☐ Twin Study
☐ Validation Studies
☐ Video-Audio Media
☐ Webcasts

FIGURE 4.18 Options available under the Customize link under Article Types.

Courtesy of National Center for Biotechnology Information.

- Click the checkbox next to **Systematic Review** (Figure 4.18) and **Show** if this is desired as an Article Type option.
- Once back at the main page, click the now available **Systematic Review** link to limit the previous search results set to just articles that are systematic reviews (**FIGURE 4.19**).



("Psoriasis"[Mesh]) AND "Drug Therapy"[Mesh]

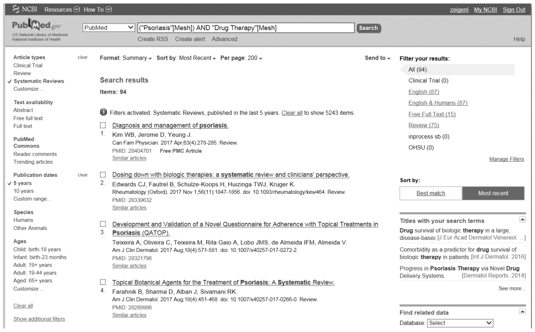
Search results

Items: 191

Filters activated: Systematic Reviews. Clear all to show 5243 items.

FIGURE 4.19 Using the Systematic Review Article Type filter to limit to just results that are systematic reviews.

Courtesy of National Center for Biotechnology Information.


NCBI Resources How To
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US National Library of Medicine
National Institutes of Health
PubMed
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Clinical Trial
Review
✓ Systematic Reviews
Customize ...
Text availability
Abstract
Free full text
Full text
PubMed Commons
Reader comments
Trending articles
Publication dates clear
✓ 5 years
10 years
Custom range...
Species
Humans
Other Animals
Ages
Child: birth-18 years
Infant: birth-23 months
Adult: 19+ years
Adult: 19-44 years
Aged: 65+ years
Customize ...
Clear all
Show additional filters
Format: Summary Sort by: Most Recent Per page: 200
Send to
Filter your results:
All (94)
Clinical Trial (0)
English (87)
English & Humans (87)
Free Full Text (15)
Review (75)
inprocess sb (0)
OHSU (0)
Manage Filters
Sort by:
Best match
Most recent
Find related data
Database: Select

("Psoriasis"[Mesh]) AND "Drug Therapy"[Mesh]

Search results

Items: 94

Filters activated: Systematic Reviews, published in the last 5 years. Clear all to show 5243 items.

☐ 1. Diagnosis and management of **psoriasis.**
Kim WB, Jerome D, Yeung J.
Can Fam Physician. 2017 Apr;63(4):278-285. Review.
PMID: 28404701 **Free PMC Article**
Similar articles

☐ 2. Dosing down with biologic therapies: a **systematic** review and clinicians' perspective.
Edwards CJ, Fautrel B, Schulze-Koops H, Huizinga TWJ, Kruger K.
Rheumatology (Oxford). 2017 Nov 1;56(11):1847-1856. doi: 10.1093/rheumatology/kew464. Review.
PMID: 28339632
Similar articles

☐ 3. Development and Validation of a Novel Questionnaire for Adherence with Topical Treatments in **Psoriasis** (QATOP).
Teixeira A, Oliveira C, Teixeira M, Rita Gaio A, Lobo JMS, de Almeida IFM, Almeida V.
Am J Clin Dermatol. 2017 Aug;18(4):571-581. doi: 10.1007/s40257-017-0272-2.
PMID: 28321796
Similar articles

☐ 4. Topical Botanical Agents for the Treatment of **Psoriasis**: A **Systematic** Review.
Farahnik B, Sharma D, Alban J, Sivamani RK.
Am J Clin Dermatol. 2017 Aug;18(4):451-468. doi: 10.1007/s40257-017-0266-0. Review.
PMID: 28289986
Similar articles

Titles with your search terms

Drug survival of biologic **therapy** in a large, disease-basec [J Eur Acad Dermatol Venereol. ...]

Comorbidity as a predictor for **drug** survival of biologic **therapy** in patients [Int J Dermatol. 2016]

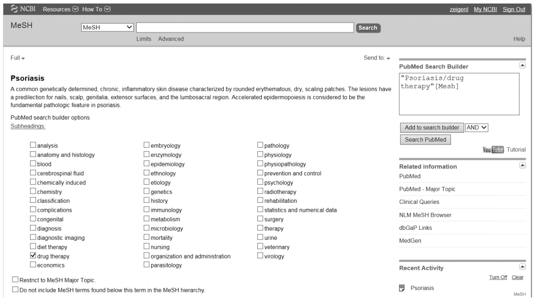
Progress in **Psoriasis Therapy** via Novel **Drug** Delivery Systems. [Dermatol Reports. 2014]

See more...

FIGURE 4.20 Using multiple limits at the same time.

Courtesy of National Center for Biotechnology Information.

11. Multiple filters can be applied at the same time. Clicking on the **5 years** limit under Publication Date limits the results further to articles on the topic that are systematic reviews that specifically have been published in the last 5 years (**FIGURE 4.20**).
12. Subheadings (different facets) can be chosen when in the MeSH record for a particular subject term.
    - In this example, doing a search on *psoriasis* with the subheading *drug therapy* will bring up additional results on the topic originally searched as MeSH terms *psoriasis* and *drug therapy* (**FIGURES 4.21** and **4.22**).
    - This additional search on the same concept in a different way can be OR-ed together with the original search to uncover additional results (see **FIGURE 4.23**).


NCBI Resources How To
zeigenl My NCBI Sign Out
MeSH
MeSH
Search
Limits Advanced
Help
Full
Send to:
PubMed Search Builder
Add to search builder
AND
Search PubMed
YouTube Tutorial
Related information
PubMed
PubMed - Major Topic
Clinical Queries
NLM MeSH Browser
dbGaP Links
MedGen
Recent Activity
Turn Off Clear
Psoriasis
MeSH

"Psoriasis/drug therapy"[Mesh]

Psoriasis

A common genetically determined, chronic, inflammatory skin disease characterized by rounded erythematous, dry, scaling patches. The lesions have a predilection for nails, scalp, genitalia, extensor surfaces, and the lumbosacral region. Accelerated epidermopoiesis is considered to be the fundamental pathologic feature in psoriasis.

PubMed search builder options

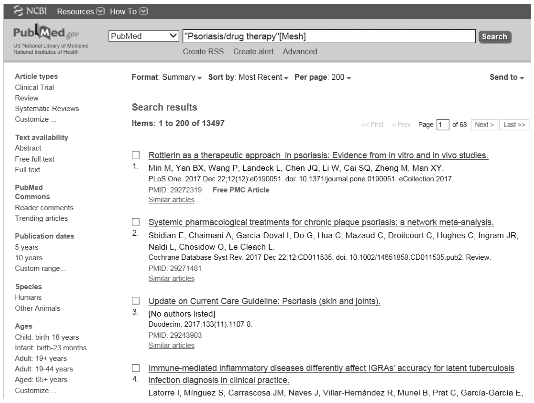
Subheadings:

☐ analysis
☐ anatomy and histology
☐ blood
☐ cerebrospinal fluid
☐ chemically induced
☐ chemistry
☐ classification
☐ complications
☐ congenital
☐ diagnosis
☐ diagnostic imaging
☐ diet therapy
☑ drug therapy
☐ economics
☐ embryology
☐ enzymology
☐ epidemiology
☐ ethnology
☐ etiology
☐ genetics
☐ history
☐ immunology
☐ metabolism
☐ microbiology
☐ mortality
☐ nursing
☐ organization and administration
☐ parasitology
☐ pathology
☐ physiology
☐ physiopathology
☐ prevention and control
☐ psychology
☐ radiotherapy
☐ rehabilitation
☐ statistics and numerical data
☐ surgery
☐ therapy
☐ urine
☐ veterinary
☐ virology

☐ Restrict to MeSH Major Topic.
☐ Do not include MeSH terms found below this term in the MeSH hierarchy.

FIGURE 4.21 MeSH subheadings for the MeSH heading Psoriasis.

Courtesy of National Center for Biotechnology Information.


NCBI Resources How To
PubMed.gov
US National Library of Medicine
National Institutes of Health
PubMed
Search
Create RSS Create alert Advanced
Article types
Clinical Trial
Review
Systematic Reviews
Customize ...
Text availability
Abstract
Free full text
Full text
PubMed Commons
Reader comments
Trending articles
Publication dates
5 years
10 years
Custom range...
Species
Humans
Other Animals
Ages
Child: birth-18 years
Infant: birth-23 months
Adult: 19+ years
Adult: 19-44 years
Aged: 65+ years
Customize ...
Format: Summary Sort by: Most Recent Per page: 200
Send to
<< First < Prev Page 1 of 68 Next > Last >>

"Psoriasis/drug therapy"[Mesh]

Search results

Items: 1 to 200 of 13497

☐ 1. Rottlerin as a therapeutic approach in psoriasis: Evidence from in vitro and in vivo studies.
Min M, Yan BX, Wang P, Landeck L, Chen JQ, Li W, Cai SQ, Zheng M, Man XY.
PLoS One. 2017 Dec 22;12(12):e0190051. doi: 10.1371/journal.pone.0190051. eCollection 2017.
PMID: 29272319 **Free PMC Article**
Similar articles

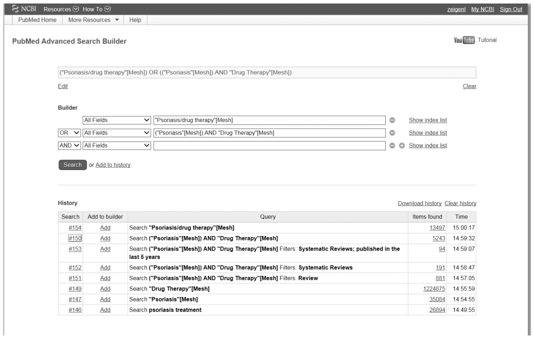
☐ 2. Systemic pharmacological treatments for chronic plaque psoriasis: a network meta-analysis.
Sbidian E, Chaimani A, Garcia-Doval I, Do G, Hua C, Mazaud C, Droitcourt C, Hughes C, Ingram JR, Naldi L, Chosidow O, Le Cleach L.
Cochrane Database Syst Rev. 2017 Dec 22;12:CD011535. doi: 10.1002/14651858.CD011535.pub2. Review.
PMID: 29271481
Similar articles

☐ 3. Update on Current Care Guideline: Psoriasis (skin and joints).
[No authors listed]
Duodecim. 2017;133(11):1107-8.
PMID: 29243903
Similar articles

☐ 4. Immune-mediated inflammatory diseases differently affect IGRAs' accuracy for latent tuberculosis infection diagnosis in clinical practice.
Latorre I, Mínguez S, Carrascosa JM, Naves J, Villar-Hernández R, Muriel B, Prat C, García-García E,

FIGURE 4.22 Results of searching on MeSH term Psoriasis with the subheading drug therapy.

Courtesy of National Center for Biotechnology Information.


NCBI Resources How To
zeigenl My NCBI Sign Out
PubMed Home More Resources Help
YouTube Tutorial
Edit
Clear
Builder
All Fields
OR
AND
Show index list
Search
or Add to history
Download history Clear history

PubMed Advanced Search Builder

("Psoriasis/drug therapy"[Mesh]) OR (("Psoriasis"[Mesh]) AND "Drug Therapy"[Mesh])

"Psoriasis/drug therapy"[Mesh]

("Psoriasis"[Mesh]) AND "Drug Therapy"[Mesh]

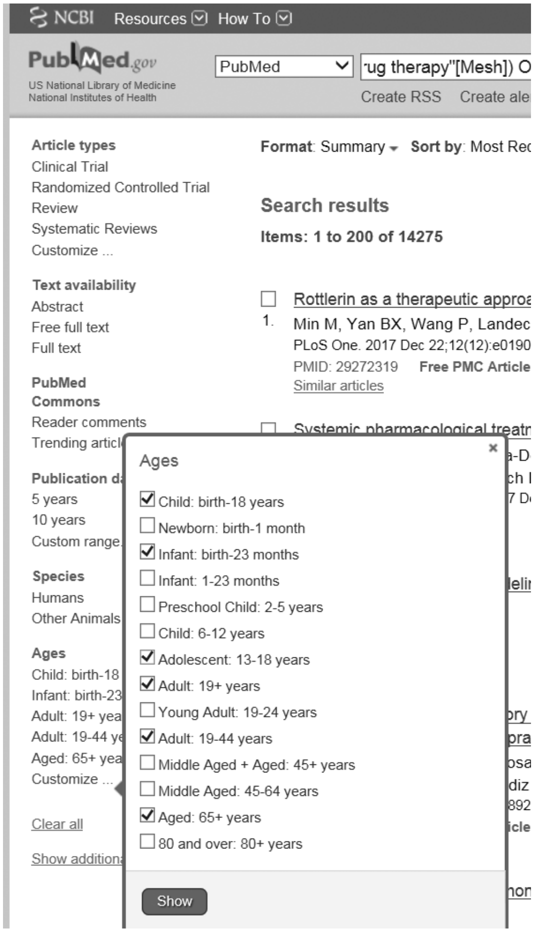
History

Search	Add to builder	Query	Items found	Time
#154	Add	Search **"Psoriasis/drug therapy"[Mesh]**	13497	15:00:17
#150	Add	Search **("Psoriasis"[Mesh]) AND "Drug Therapy"[Mesh]**	5243	14:59:32
#153	Add	Search **("Psoriasis"[Mesh]) AND "Drug Therapy"[Mesh]** Filters: **Systematic Reviews; published in the last 5 years**	94	14:59:07
#152	Add	Search **("Psoriasis"[Mesh]) AND "Drug Therapy"[Mesh]** Filters: **Systematic Reviews**	191	14:58:47
#151	Add	Search **("Psoriasis"[Mesh]) AND "Drug Therapy"[Mesh]** Filters: **Review**	881	14:57:05
#149	Add	Search **"Drug Therapy"[Mesh]**	1224875	14:55:59
#147	Add	Search **"Psoriasis"[Mesh]**	35084	14:54:55
#146	Add	Search **psoriasis treatment**	26894	14:49:55

FIGURE 4.23 Combining a new MeSH term with existing MeSH terms that have already been searched.

Courtesy of National Center for Biotechnology Information.

13. For limits related to age group, click on the **Show additional filters** link in the left-hand navigation, then the checkbox **Age**.
    - Once the Age category is available, click on the desired age range or on the **Customize** link to bring up additional age ranges to make available for filtering (see **FIGURE 4.24**).
    - Utilizing limits produces a much more focused result set that is more relevant and more manageable to review and evaluate (see **FIGURE 4.25**).


NCBI
Resources
How To
PubMed.gov
US National Library of Medicine
National Institutes of Health
PubMed
Create RSS
Create ale
Show

ug therapy"[Mesh]) O

Article types
Clinical Trial
Randomized Controlled Trial
Review
Systematic Reviews
Customize ...

Text availability
Abstract
Free full text
Full text

PubMed Commons
Reader comments
Trending articl

Publication d
5 years
10 years
Custom range

Species
Humans
Other Animals

Ages
Child: birth-18
Infant: birth-23
Adult: 19+ yea
Adult: 19-44 ye
Aged: 65+ yea
Customize ...

Clear all

Show addition

Format: Summary **Sort by**: Most Rec

Search results

Items: 1 to 200 of 14275

☐ 1. Rottlerin as a therapeutic approa
Min M, Yan BX, Wang P, Landec
PLoS One. 2017 Dec 22;12(12):e0190
PMID: 29272319 **Free PMC Article**
Similar articles

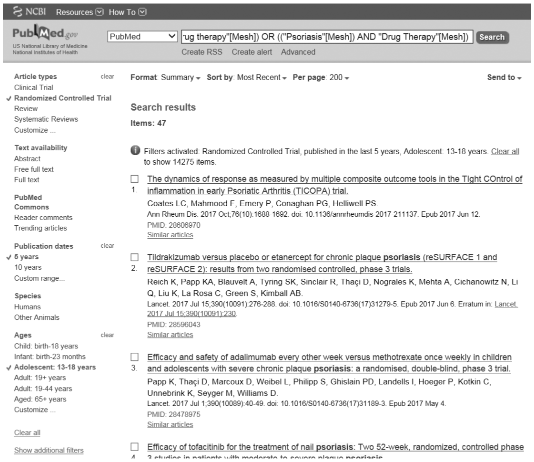
☐ Systemic pharmacological treatr

Ages

☑ Child: birth-18 years
☐ Newborn: birth-1 month
☑ Infant: birth-23 months
☐ Infant: 1-23 months
☐ Preschool Child: 2-5 years
☐ Child: 6-12 years
☑ Adolescent: 13-18 years
☑ Adult: 19+ years
☐ Young Adult: 19-24 years
☑ Adult: 19-44 years
☐ Middle Aged + Aged: 45+ years
☐ Middle Aged: 45-64 years
☑ Aged: 65+ years
☐ 80 and over: 80+ years

FIGURE 4.24 Bringing up options for age range limits.

Courtesy of National Center for Biotechnology Information.



ug therapy"[Mesh]) OR (("Psoriasis"[Mesh]) AND "Drug Therapy"[Mesh])

Article types clear
Clinical Trial
✓ **Randomized Controlled Trial**
Review
Systematic Reviews
Customize ...

Text availability
Abstract
Free full text
Full text

PubMed Commons
Reader comments
Trending articles

Publication dates clear
✓ **5 years**
10 years
Custom range...

Species
Humans
Other Animals

Ages clear
Child: birth-18 years
Infant: birth-23 months
✓ **Adolescent: 13-18 years**
Adult: 19+ years
Adult: 19-44 years
Aged: 65+ years
Customize ...

Clear all

Show additional filters

Format: Summary **Sort by**: Most Recent **Per page**: 200

Search results

Items: 47

Filters activated: Randomized Controlled Trial, published in the last 5 years, Adolescent: 13-18 years. Clear all to show 14275 items.

☐ 1. The dynamics of response as measured by multiple composite outcome tools in the TIght COntrol of inflammation in early Psoriatic Arthritis (TICOPA) trial.
Coates LC, Mahmood F, Emery P, Conaghan PG, Helliwell PS.
Ann Rheum Dis. 2017 Oct;76(10):1688-1692. doi: 10.1136/annrheumdis-2017-211137. Epub 2017 Jun 12.
PMID: 28606970
Similar articles

☐ 2. Tildrakizumab versus placebo or etanercept for chronic plaque **psoriasis** (reSURFACE 1 and reSURFACE 2): results from two randomised controlled, phase 3 trials.
Reich K, Papp KA, Blauvelt A, Tyring SK, Sinclair R, Thaçi D, Nograles K, Mehta A, Cichanowitz N, Li Q, Liu K, La Rosa C, Green S, Kimball AB.
Lancet. 2017 Jul 15;390(10091):276-288. doi: 10.1016/S0140-6736(17)31279-5. Epub 2017 Jun 6. Erratum in: Lancet. 2017 Jul 15;390(10091):230.
PMID: 28596043
Similar articles

☐ 3. Efficacy and safety of adalimumab every other week versus methotrexate once weekly in children and adolescents with severe chronic plaque **psoriasis**: a randomised, double-blind, phase 3 trial.
Papp K, Thaçi D, Marcoux D, Weibel L, Philipp S, Ghislain PD, Landells I, Hoeger P, Kotkin C, Unnebrink K, Seyger M, Williams D.
Lancet. 2017 Jul 1;390(10089):40-49. doi: 10.1016/S0140-6736(17)31189-3. Epub 2017 May 4.
PMID: 28478975
Similar articles

☐ 4. Efficacy of tofacitinib for the treatment of nail **psoriasis**: Two 52-week, randomized, controlled phase

FIGURE 4.25 Results of search with multiple limits applied.

Courtesy of National Center for Biotechnology Information.

CINAHL

Cumulative Index to Nursing and Allied Health Literature (CINAHL) is a database that covers content in the subject areas of nursing and allied health. CINAHL is available only through an interface with the database vendor EBSCO. Many academic libraries, hospitals, and even some public libraries purchase access to CINAHL. Whereas MEDLINE includes records of only journal articles, CINAHL includes other formats such as dissertations, patient education materials, and tests and evaluation instruments.

As CINAHL is a proprietary database, no screenshot can be included here. However, some videos on YouTube can be referenced to learn more.

Like MEDLINE, the CINAHL database includes a controlled vocabulary of subject headings. Depending on where CINAHL is used, the interface may be set to default to searching the CINAHL vocabulary. If that is not the case, the controlled vocabulary can be used to combine heading terms. CINAHL can also be used to search by author or to access articles from a specific journal or articles of a specific publication type. The subject content of CINAHL overlaps in some areas with the subject content of MEDLINE, so some of the same journal articles are present in both databases. It is important to search both databases, however, to achieve comprehensive results. The basic CINAHL database includes very limited full-text information. At an academic or hospital library, the site may have purchased an expanded version of CINAHL that includes links to many full-text articles. Other full-text information may be accessible because the library provides links to articles in other subscription journals. If a particular article cannot be accessed, it may be possible to order it through interlibrary loan or directly from the publisher.

PsycINFO

PsycINFO, produced by the American Psychological Association (APA), is a database that covers content in the areas of behavioral science and mental health. PsycINFO is available through database vendors such as EBSCO, Ovid, or ProQuest at institutions that subscribe to the database. Individual subscriptions are also available through the APA. As PsycINFO is a proprietary database, no screenshot can be included here. However, some videos on YouTube can be referenced to learn more.

PsycINFO also uses a controlled vocabulary of keywords to help locate citations relevant to a search. The database can be searched by author, research area, or publication type.

Sites that support PsycINFO, such as an academic or hospital library, may have purchased an expanded version of the database that includes links to many full-text articles. Other full-text information may be accessible because the library provides links to articles in other subscribed journals. If a particular article cannot be accessed, it may be possible to order it through interlibrary loan or directly from the publisher.

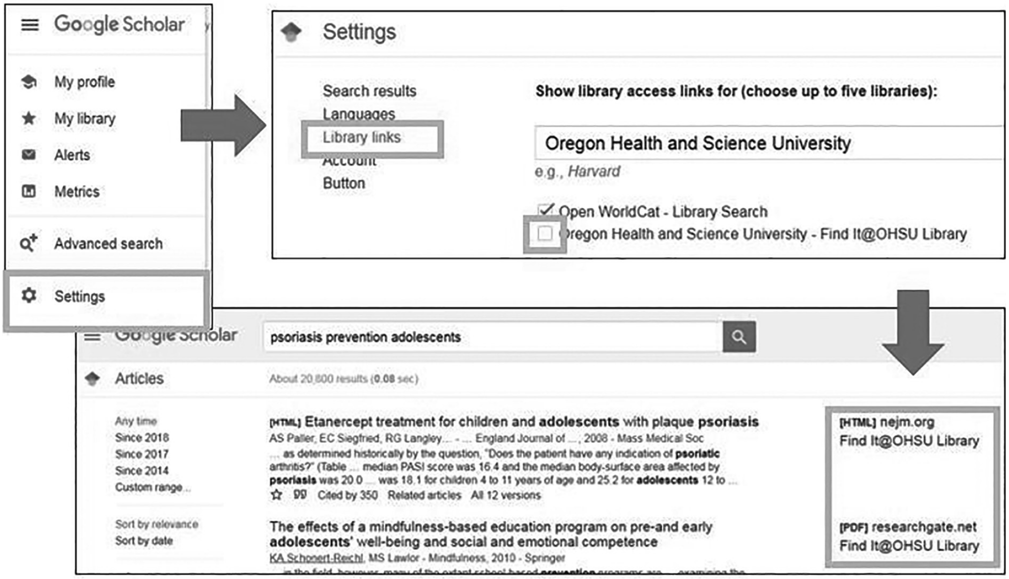
Google Scholar

Although using only Google or another general Internet search engine to find information for research is ill-advised for doing real research, Google Scholar (a subset of Google available at http://scholar.google.com) can be very helpful in finding scholarly literature across many disciplines and sources including journal articles, abstracts, and theses. It is, in fact, an essential, but insufficient, part of finding grey literature.[13] Search results are ranked on some criteria, including where the full-text article was published, who wrote it, and how often and how recently it has been cited in other scholarly literature. Part of Google Scholar's algorithm for results retrieval includes the "popularity" of an article: articles that have been linked to more rise higher on the set of search results; therefore, Google Scholar search results tend to favor articles that are slightly older. If only Google Scholar is used for a literature search, newer and yet to be cited articles are often missed.

Google Scholar has both a friendly "Google-like" option and an advanced feature, which increases the accuracy and effectiveness of the search. Although controlled vocabulary is not used in Google Scholar, the advanced feature supports the specification of words or phrases that must (or must not) appear in the article. Searches can be limited by the author, source, date, and PDF format, and by broad subject areas such as medicine, pharmacology, and veterinary science. Some articles may be available for free, depending on the source. Otherwise, a library that subscribes to the journal can provide access to specific articles, which may also be purchased from the publisher or ordered through interlibrary loan. If your institution has created a connection between Google Scholar and your library catalog, you can configure Google Scholar to recognize articles from search results that are available from a journal to which your institution's library subscribes. It will then allow you to click through to the full-text article. To configure Google Scholar to do this, from within Google Scholar, go to Settings, then Library Links, search for your institutional library name, click on the checkbox next to the name and click "Save" (**FIGURE 4.26**). Your Google Scholar listing should now have some button or link next to some of the citations that display "Find It in Your Library" or something similar.

Web of Science and Scopus

Web of Science and Scopus are databases that contain information gathered from thousands of scholarly journals in all areas of research. Web of Science is available only through access to the ISI Web of Knowledge set of database resources. Scopus is only available through Elsevier. Many academic libraries subscribe to either the Web of Knowledge or to Scopus but do not usually subscribe to both. Because these databases are searching across many disciplines, they cannot be searched using subject terms (controlled vocabulary), but can only be searched by keywords. The word "mercury" will mean something different in an environmental science database than it does in a physics/astronomy database and the types of broad databases discussed here will not be able to distinguish them. In other words, you may get some slightly



Show library access links for (choose up to five libraries):

Oregon Health and Science University

e.g., *Harvard*

☑ Open WorldCat - Library Search

☐ Oregon Health and Science University - Find It@OHSU Library

psoriasis prevention adolescents

About 20,800 results (0.08 sec)

[HTML] Etanercept treatment for children and **adolescents** with plaque **psoriasis**
AS Paller, EC Siegfried, RG Langley... - ... England Journal of ..., 2008 - Mass Medical Soc
... as determined historically by the question, "Does the patient have any indication of **psoriatic** arthritis?" (Table ... median PASI score was 16.4 and the median body-surface area affected by **psoriasis** was 20.0 ... was 18.1 for children 4 to 11 years of age and 25.2 for **adolescents** 12 to ...
☆ 99 Cited by 350 Related articles All 12 versions

[HTML] nejm.org
Find It@OHSU Library

The effects of a mindfulness-based education program on pre-and early **adolescents'** well-being and social and emotional competence
KA Schonert-Reichl, MS Lawlor - Mindfulness, 2010 - Springer

[PDF] researchgate.net
Find It@OHSU Library

FIGURE 4.26 Setting up Google Scholar to connect to full text from your institution.

"fuzzy" results of things that only seem tangentially related to your topic. This is part of why it is very important to determine the concepts you are seeking, and the specific intersection of those concepts as adding in terms for these concepts can help focus your search results to more of what you want.

In addition to allowing a search across a wider array of disciplines than is possible from discipline-specific resources, Web of Science and Scopus can also provide additional information on journals or authors/researchers. Referencing these pieces of information, such as Impact Factor, CiteScore, SCImago Journal Rank, SNIP, or others can provide a sense of the relative prominence of a peer-reviewed journal within a particular field. These databases can also be utilized for tracking on additional publications by a specific researcher and information like that researcher's h-index (a measure of their scholarly productivity), co-authors, and how many times that researcher's works have been cited.[8] Additionally, searching for a combination of affiliation (an institution) and a research topic can help point to the individuals at an institution who are working in a particular area of research.

Web of Science and Scopus can be searched by the subject topic or by the author, but their great strength comes in searching for cited references. For example, a search on a particular topic in PubMed may yield a very relevant article that happens to be a bit old. If interested in what articles have come out more recently related to that topic, the researcher can look up that article in Web of Science or Scopus, which can then indicate the articles that have cited the relevant article since it was published. Likewise, a listing of search results can be sorted in a number of ways including reverse chronological order (newer articles first) or by "Cited by" with the most highly cited articles first. These articles also have links showing which articles have cited the most cited articles. In this way, the researcher can track a scholarly conversation forward through time to see which researchers influenced the conversation in a particular way about a topic. Access to full text of articles in Web of Science and Scopus depends on the subscriptions purchased by the library or institution where the database is used. Articles from journals that are not available can sometimes be ordered through interlibrary loan or purchased directly from the publisher.

Other databases beyond the ones covered here should be considered as part of any comprehensive search depending on the subject of the search question.

Writing the Literature Review

Once all of the information is gathered, a literature review can be written as a summary of what is known (and not known) in the research topic area. This review is a discussion of previous research, not a list of references. The purpose of writing a review is **not** to copy and paste from other sources, but to utilize information from a variety of sources to synthesize and articulate your ideas (**FIGURE 4.27**). Literature reviews begin with a brief introduction summarizing the research question, the resources used for the literature review, and the search strategies. Then the results of the review are summarized. Be sure to discuss key points, reference quoted information, and include gaps in the existing research as well as areas of weakness or controversy. The reader should be made aware of the pertinent points of your research question and the research history on which they are built. Before the conclusion, readers should understand why answering this research question is important.

Additional hints for writing a good literature review are available on the Internet from writing centers at many academic institutions. Research in professional journals also provides valuable examples of literature reviews regarding their content and how they are written.

Summary

The review of the literature is a key component of any research project. It is incumbent on the investigator to do a concise and comprehensive review. The review must provide information on what is known and allows the investigator to define further what needs to be known. Understanding and using literature databases are skills that must be

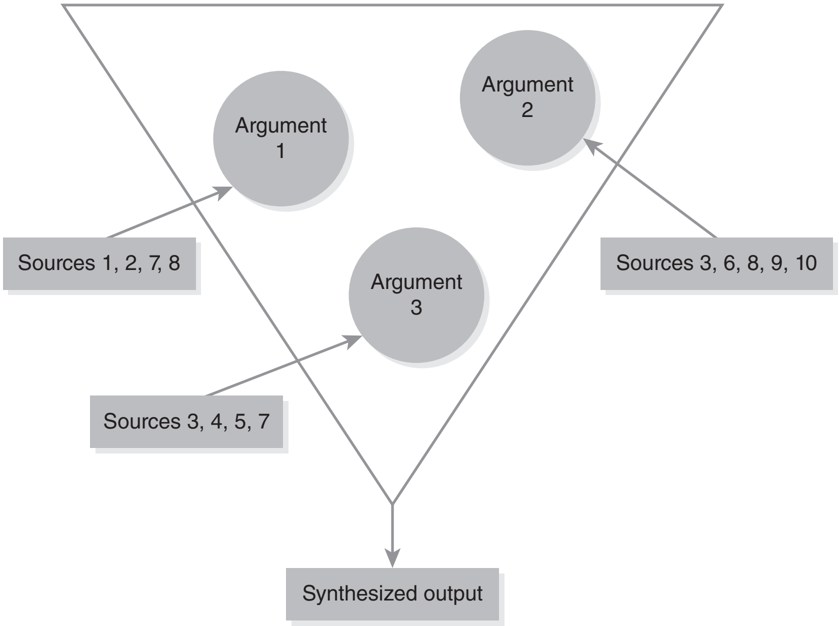


FIGURE 4.27 Synthesizing information from a variety of sources to provide support and evidence for your arguments.

mastered. Investigators must understand the content of different databases and use those related to the research project. Without a literature review, there can be no project.

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1. Baker JD. The purpose, process, and methods of writing a literature review. *Aorn J.* 2016;103(3):265–269.
2. Wilton NK, Slim AM. Application of the principles of evidence-based medicine to patient care. *South Med J.* 2012;105(3):136–143.
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5. Cooper C, Varley-Campbell J, Booth A, Britten N, Garside R. Systematic review identifies six metrics and one method for assessing literature search effectiveness but no consensus on appropriate use. *J Clin Epidemiol.* 2018.
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11. Schardt C, Adams MB, Owens T, Keitz S, Fontelo P. Utilization of the PICO framework to improve searching PubMed for clinical questions. *BMC Med Inform Decision Making.* 2007;7.
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13. Haddaway NR, Collins AM, Coughlin D, Kirk S. The role of Google scholar in evidence reviews and its applicability to Grey Literature Searching. *PLoS One.* 2015;10(9):e0138237.

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CHAPTER 5

The Systematic Review

Margaret J. Foster, MS, MPH

CHAPTER OVERVIEW

This chapter provides an overview of the steps to complete a systematic review. A *systematic review* is a research method where studies are collected, assessed, and synthesized using rigorous and transparent methods to minimize bias. If the review includes combining data from many studies into one calculated outcome, it is called a *meta-analysis*. Systematic reviews perform an important role in evidence-based practices by providing practitioners with a concise view of a specific health issue. Also, reviews translate primary research into outputs that are readily understood by policymakers, funders, patients, and the public.

LEARNING OBJECTIVES

- Identify the five main types of systematic reviews.
- Write a research question in PICO or another appropriate framework.
- List the main steps used in a systematic review.
- Develop a bibliographic database search.
- Define and discuss the concept of *gray literature*.
- Contrast the purpose and interpretation of a forest plot and a funnel plot.

The Systematic Review

What Is a Systematic Review?

As the volume of health sciences information, such as published articles and data, has grown rapidly over the past decade, so has the need for evidence-based summaries that review studies in a particular area. The typical literature review does not meet this need because many are lacking in rigorous methods, cannot be properly evaluated due to poor reporting standards, and/or have conclusions that are subjective and biased.[1] This deficit led to the development of the systematic review as a more reliable method to gather, analyze, and synthesize studies to answer a specific research question using rigorous and transparent methods. Systematic reviews are a "powerful tool to help clinicians use evidence for patient care decisions"[2] when conducted using appropriate standards.

Role in Research and Evidence-Based Practice

Single, primary studies include a narrowly defined group of patients, measure few outcomes, and can contradict other studies' results.[3] Evidence-based practice calls for health practitioners to answer questions by gathering and analyzing data, but time constraints limit the amount of evidence that most practitioners can synthesize. By utilizing systematic reviews, practitioners receive a more comprehensive look at a situation than one individual study can provide and a clearer perspective of previous research. Without this understanding, new studies could be conducted that are unnecessary, inappropriate, or even unethical.[4] Authors of reviews can also identify gaps in current research and organize evidence for decision making. Gaps in the literature are those instances when a question has never been explored, has not been addressed with a particular population or intervention, or has been studied but with questionable/outdated methods. Researchers can then address these holes in the evidence by conducting new primary studies.

Organizations Leading Systematic Review Development

Several international and national organizations offer guidance, funding, and/or a forum for producing or disseminating systematic reviews. The most notable is the Cochrane Collaboration, which was founded in 1992 as a nonprofit international organization with the mission to "promote evidence-informed health decision-making by producing high-quality, relevant, accessible systematic reviews and other synthesized research evidence."[5] These reviews are usually conducted by a group of expert volunteers and focus on clinical questions, although recently reviews centering on other types of questions such as population health and public policy have been published. The procedures for conducting a Cochrane review are detailed in the *Cochrane Handbook*, which is available for free online.[6] Other leading organizations include the Agency for Healthcare Research and Quality (AHRQ), Joanna Briggs Institute (JBI), and Centre for Reviews and Dissemination (CRD).

Types of Reviews

More than 20 types of systematic reviews have been described, varying on the type of evidence included, the scope of the search, the depth of assessment, and the type of synthesis presented.[1,4,7] The general systematic review and meta-analysis have already been defined. Four other types include:

- *Scoping or Mapping review:* A broad review, gathering studies on a single topic and providing some categorizing, usually without assessing methods
- *Integrative review:* A review that combines qualitative and quantitative studies on a similar issue
- *Qualitative review:* A review that includes qualitative studies only
- *Realist review:* A review (add citation) that explores the underlying mechanisms of an intervention and how it works under different circumstances[8]
- *Review of reviews:* A synthesis of systematic reviews

This introduction describes steps that all reviews should conduct, although the comprehensiveness of methods will vary.

Steps of the Review

Step 1: Define and Plan the Review

Defining the review involves determining the research question, ensuring that the research question is unique by locating/assessing related reviews, detailing the purpose of the review, and planning the management of the review.

Step 1a: Frame the Question and Define Criteria

One of the primary characteristics of a systematic review (SR) that makes it different from a literature review is that the main objective is to answer a research question. Framing that question is key to ensuring that the question is specific. The narrowness of the question should be strategically gauged to produce a useful review that will be generalizable yet applicable to many patient groups. If it is too vague, it will be difficult to answer the question, collect relevant studies, or synthesize the data. For many health-related reviews, authors focus on the effectiveness of an intervention and therefore select the PICO framework, which stands for Population, Intervention, Comparison, and Outcome. The inclusion criteria are created as a list of characteristics required by a primary study to be included in the review. **TABLE 5.1** shows an example of a research question, PICO framework, and study criteria. This research question will serve as an example throughout this chapter.

There are several other frameworks to consider for systematic reviews not involving interventions. For example, the PEO framework (Population, Exposure/Factor, Outcome) can be used when exploring factors or exposures that can be beneficial or harmful (add citation). If the review is evaluating diagnostic tests, authors should select the PIRT framework (Population, Index Test(s), Reference Standard, Target condition).[9]

Step 1b: Find and Appraise Relevant Reviews

Locating and analyzing relevant reviews is necessary to determine to what extent other authors have explored a similar topic. Three types of databases can be searched for relevant reviews: subject-specific, review, and dissertation databases. *Subject-specific databases* like MEDLINE, Embase, or CINAHL collect research on a particular topic (in this case, clinical medicine), and many provide an option to limit retrieved articles to systematic reviews. To locate all potential systematic reviews in these types of databases, researchers have developed validated search filters. A search filter is a list of terms designed for a specific database and interface to retrieve all records matching a particular method type, topic, or another characteristic. A website that provides a bibliography of search filters is the InterTASC Information Specialists' Sub-Group Search Filter Resource.[10] *Review databases* collect only systematic reviews, meta-analyses, and/or review protocols (see **TABLE 5.2** for an abbreviated list). Protocols describe the proposal for a systematic review and can be published and/or registered, similar to the idea of registering a clinical trial. Lastly, *dissertation databases* collect theses and dissertations.

When searching for related reviews, begin by finding reviews that are very close to the same subject, and then continue broadening the search until at least a few reviews are found. When evaluating

TABLE 5.1 Defining the Question and Criteria

PICO Format of Question	Study Criteria
Do the published studies show that reducing screen time reduces/prevents obesity in children? ■ *Population:* Children ■ *Intervention:* Reduce screen time ■ *Comparison:* No intervention ■ *Outcome:* Reduced weight or body mass index (BMI)	The study will be included if: ■ Participants are children 2–19 years old. ■ It is a randomized controlled trial to reduce screen time. ■ It reports weight or BMI. ■ It is in English and published after 1990. ■ Its methods are appropriate according to the selected checklist.

TABLE 5.2 Free Review Databases

Provider	Database Name	Internet Address
Allied Health Evidence	Combination of four databases: Physiotherapy Evidence Database (PEDro); OTseeker (occupational therapy); speechBITE (Best Interventions and Treatment Efficacy; speech pathology); PsycBITE (Psychological Database for Brain Impairment Treatment Efficacy)	http://www.alliedhealthevidence.com
Cochrane Collaboration	Combination of six databases: Cochrane Database of Systematic Reviews (CDSR), Cochrane Central Register of Controlled Trials (CENTRAL), Cochrane Methodology Register (CMR), Database of Abstracts of Reviews of Effects (DARE), Health Technology Assessment Database (HTA), NHS Economic Evaluation Database (EED)	http://summaries.cochrane.org (subscription version also available)
Health Evidence	Database of reviews of health promotion interventions	http://www.healthevidence.org
PubMed Health	Includes systematic reviews from PubMed, Cochrane, and other resources starting from the year 2000	https://www.ncbi.nlm.nih.gov/pubmedhealth/
Evidence for Policy and Practice Information and Co-ordinating Centre (EPPI-Centre)	Includes three databases of health-related reviews: Bibliomap; Database of Promoting Health Effectiveness Reviews (DoPHER); Trials Register of Promoting Health Interventions (TRoPHI)	http://eppi.ioe.ac.uk

a related review, record the research question, criteria, resources searched, years covered by the search, synthesis type, main conclusion, quality assessment, and validity of the findings, to easily compare the reviews. Several checklists have been developed for appraising the quality of systematic reviews, including the Risk of Bias of Systematic reviews, Critical Appraisal Skills Programme (CASP) Systematic Review Checklist, and A Measurement Tool to Assess Systematic Reviews (AMSTAR).[11,12,13] All of the checklists evaluate these elements: appropriateness of the question and criteria, comprehensiveness of the search, rigor of the critical assessment, and quality of the synthesis and analysis. After examining the related reviews, the research question or criteria may need to be altered so that the review will be unique or, if not distinctive, an update of a previous review.

Step 1c: Define the Purpose of the Review

It is important to establish the main objective of the systematic review as well as its scope, final products, and appropriate standards. The main objective of the systematic review depends on its type. For example, scoping reviews aim to characterize the size of existing literature, qualitative reviews seek to generate or explore theory, and most traditional reviews try to test a hypothesis. The scale or scope of the review can vary between taking a representative approach (searching for just a few resources) or a comprehensive approach (conducting a wide sweeping search).[14] By defining the scope at the beginning of the review process, authors can prevent "scope creep"—the slow, and sometimes unrealized, adjustments that often occur to the study's goals, scale, or timeline.[7] The author(s) should determine the products of the review, which could include a protocol, a journal article, and/or an executive summary. For each of these outputs, authors can select from the several available appropriate standards. Many authors in clinical medicine rely on the *Cochrane Handbook* for systematic review procedures and on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines for the report of a protocol and/or completed review.[6,15]

Step 1d: Project Management

Systematic review developers should consider three main areas in managing the project—developing a team, setting a timeline, and choosing software. A systematic review team should include experts on the topic of the review as well as in searching, systematic review methods, and statistics (if appropriate). If the review is done by a single author, the author should find experts to consult throughout the process. Standards of the National Academies of Sciences, Engineering, and Medicine (formerly known as Institute of Medicine) requires that systematic review searches be developed by expert searchers.[16] In addition to experts, some systematic review authors choose to include stakeholders at some point in the process to provide different perspectives and to increase the possibility that the review's findings will have wide-reaching effects.[4] The time investment in a systematic review is significant and for the most part, depends on the size of the evidence base and depth of the search and assessment. The *Cochrane Handbook* shows a timeline to complete a review within a year.[6] Software selection will include choosing tools for various activities: project management, file storage, collecting citations, coding text/data, and statistical calculations. Specialized software applications have been designed for conducting all or part of a systematic review. (See **TABLE 5.3** for examples.) Several factors will affect selection: accessibility of the software,

TABLE 5.3 Examples of Software for Various Processes in the Review

Name	Organization	Internet Address
Covidence	Covidence, partnered with Cochrane Collaboration	https://www.covidence.org/
DistillerSR	Evidence Partners	https://www.evidencepartners.com
EPPI-Reviewer	Evidence for Policy and Practice Information and Co-ordinating Centre (EPPI-Centre)	https://eppi.ioe.ac.uk/cms/er4/
Systematic Review Data Repository (SRDR)	Agency for Healthcare Research and Quality (AHRQ)	https://srdr.ahrq.gov/
RevMan	Cochrane Collaboration	http://community.cochrane.org/help/tools-and-software/revman-5
System for the Unified Management, Assessment and Review of Information (SUMARI)	Joanna Briggs Institute	https://www.jbisumari.org/
NVivo	QSR International	http://www.qsrinternational.com/nvivo/nvivo-products

customizability, number of functions it can perform, the ability of the software to accommodate multiple users, and cost. To explore other software, visit the Systematic Review Toolbox, a database that collects potential software for reviews.[17]

Step 2: Bibliographic Database Searches (Part 1 of Search)

Performing an efficient and thorough search is important for three reasons: to endeavor to locate all relevant articles, to minimize bias in the review, and to minimize the number of irrelevant articles retrieved. Systematic review searches follow a sequence of four phases: develop the search, evaluate the search, save and document the final search, and de-duplicate and translate for other databases. At the end of the search, all of the retrieved articles will be screened, labeled, and assessed. Authors are encouraged to collaborate with a librarian to ensure that the appropriate resources for the topic are searched with a thorough list of search terms and phrases. An important set of standards to consult is the Methodological Expectations of Cochrane Intervention Reviews (MECIR) of the Cochrane Collaboration which covers conducting and reporting protocols and reviews.[18]

Step 2a: Develop the Search

First, list the databases to be searched, making sure to include databases that cover a wide range of disciplines likely to be interested in the review topic. The *Cochrane Handbook* suggests at least three databases be searched: MEDLINE, Embase, and Cochrane CENTRAL.[6] By searching more than one database, researchers ensure that the search has covered a broad range of biomedical journals. Also, consider other databases to cover the topic fully- for example ERIC for topics concerning educational settings, PsycINFO for psychological topics, or SportDISCUS for questions around sports or rehabilitation.

Second, select those concepts from the inclusion criteria that are appropriate for the search. For most clinical reviews, those concepts are the designated population, health issue, intervention, and the study type (if appropriate). **TABLE 5.4** illustrates an example. List synonyms for each concept, including clinical and natural language terms as well as alternative endings and spellings for all terms. Collect search terms from those provided in previous reviews, by consultation with experts, and from any articles already located that will be included. When considering selecting a study type as a search concept, it is important to consider if the study type is a well-established, standardized type (such as a randomized controlled trial) or a vaguely described type such as an evaluation of a program. Most standardized study types have validated search filters for Medline, Embase, and other databases. Visit the InterTASC Information Specialists' Sub-Group Search Filter Resource website for a current list.[10]

Next, select the most important database for the review topic, which is usually MEDLINE for biomedical topics. The *Cochrane Handbook* calls for searching for concepts using keywords and thesaurus terms, such as MeSH terms for MEDLINE or emtree for Embase. MeSH stands for Medical Subject Headings and are a set list of terms arranged into hierarchal trees of subjects, branching from one overall concept to more specific concepts. (See **FIGURE 5.1** for an example of the MeSH *body weight* and its branches.) Searchers can select all of the terms along one branch by selecting "explode." For example, if the term *overweight* was selected and exploded, that would capture all of those terms marked with overweight and all of the terms down the branch. By combining keywords and MeSH terms, the search will retrieve more relevant articles than by using only one of these fields. See **FIGURE 5.2** for an example of combining these fields for the term *obesity*.

Step 2b: Evaluating the Search

The search will typically have many drafts, each undergoing careful assessment, with necessary changes incorporated before settling on the most effective search. When evaluating the first draft of the search, survey the first 50–100 results and collect any article that matches all

TABLE 5.4 Developing a Search in Medline

1. Define concepts to be searched	Concept 1: Children Concept 2: Screen time Concept 3: Obesity
2. List synonyms	Concept 1: Children or adolescents or teenagers or youth or toddlers or preschool Concept 2: Screen time or screen media or video game or television or TV or computer Concept 3: Obesity or obese or overweight
3. Add truncations and alternate spellings	Concept 1: Child* or adolescen* or teen* or youth* or toddler* or preschool* Concept 2: Screen time* or screen media* or video game* or videogame* or television or TV or computer* Concept 3: Obes* or overweight*
4. Find MeSH terms for each concept	Concept 1: *exp child* or *exp adolescent* Concept 2: *exp video games* or *exp television* or *exp computer* Concept 3: *exp overweight*
5. Combine keywords with MeSH terms with OR; then combine all terms for each concept with AND	<child* or adolescen* or teen* or youth* or toddler* or preschool* or *exp child* or *exp adolescent*> AND <screen time* or screen media* or video game* or videogame* or television or tv or computer OR *exp video games* or *exp television* or *exp computer*> AND <obes* or overweight* or *exp overweight*>

MeSH are in italics.

* returns any records with words starting with search string (e.g., adolesc* returns adolescent, adolescents, adolescence) exp stands for explode, will retrieve all studies labeled with this MeSH term and any MeSH terms under it in the hierarchy

Data from: Foster M. Introduction to systematic reviews for healthcare design. *Health Env Res Design J*. 2013;7(1):143–154.

criteria. Screen these articles for other keywords and MeSH terms that should be added to the search. A tool that can be very helpful at this point is the Yale MeSH Analyzer, a free online tool which displays the MeSH terms of up to 20 citations to aid in the selection of terms.[19] It is also important to plan for a peer review of the search by another expert search to meet the standards from the National Academies of Sciences, Engineering, and Medicine.[16] The author(s) may consult one or more checklists to aid in search evaluation, such as the Peer Reviews Electronic Search Strategies (PRESS), created by the Canadian Agency for Drugs and Technologies in Health.[20] The PRESS list looks at the translation of criteria into search terms, correct use of Boolean and proximity operators, appropriate use of index terms, the inclusion of all important keywords and spelling variants, spelling/syntax errors, limits, and correct translation of the search into other databases.

Step 2c: Save and Document the Search

Whenever possible, save the search within the platform it was searched (i.e., NCBI [PubMed], EBSCO, Proquest, OvidSP) so that it can be easily rerun at a later date and/or altered as necessary. Also, the exact search should be copied and stored in a separate location. Other information to record: database name, platform, date of the

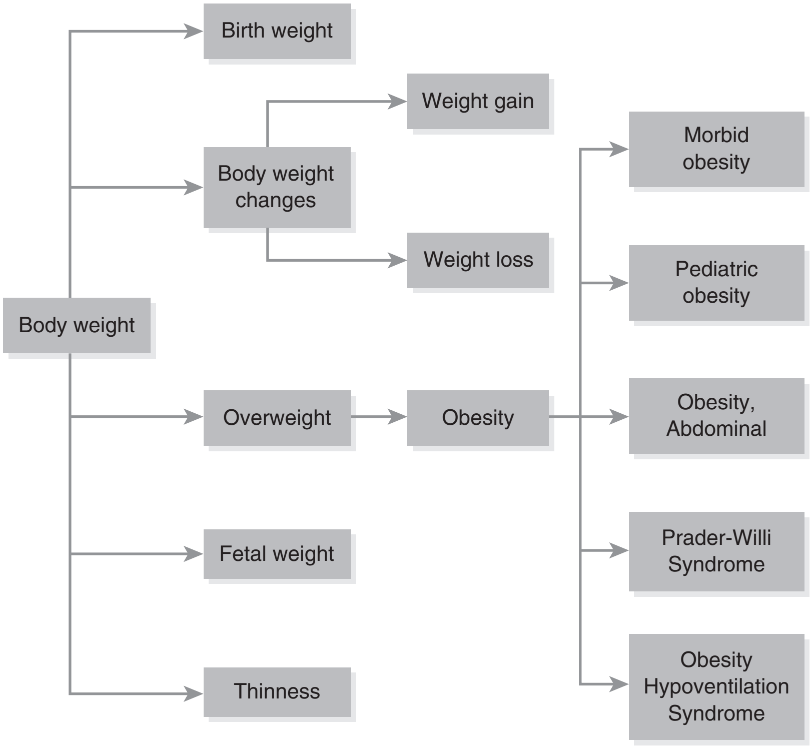
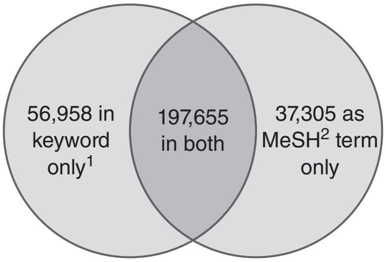

Birth weight
Weight gain
Morbid obesity
Body weight changes
Weight loss
Pediatric obesity
Body weight
Overweight
Obesity
Obesity, Abdominal
Fetal weight
Prader-Willi Syndrome
Thinness
Obesity Hypoventilation Syndrome

FIGURE 5.1 MeSH tree for *body weight*.



[1] keywords: obese or obesity
[2] MeSH term: obesity

FIGURE 5.2 Number of articles with obesity as a concept in various fields.

search, years covered, limits applied, number of articles retrieved, and new articles added.[6]

Step 2d: De-duplicate and Translate for Other Databases

Translating the original search into other databases can be tricky, especially when moving to different platforms. Also, some resources have very limited options for searching, such as only offering browsing and lacking export options. Consulting an information specialist can help with these issues.

Step 3: Appraisal

The appraisal process involves narrowing down the retrieved articles to those studies that will be critically analyzed, coded, and ultimately synthesized. Screening is conducted in multiple steps, evaluating the articles increasingly in-depth as they pass through each step, by title/abstract, full text, and then appraisal of methods. Each part of the process should be piloted with a small group of articles to ensure that everyone on the team follows the process in a similar way.

Step 3a: Screening

In developing the screening process, decide on screening questions and labels, who will screen,

TABLE 5.5 Screening Questions

Question	Label
1. Is this article in English? 2. Is it published after 1989? 3. Is it about reducing screen time in children? 4. Does it include outcome measure—weight, BMI?	■ *Included:* Yes to all questions. ■ *Maybe:* Unsure. ■ *Excluded 1:* If no to question 1, stop screening. ■ *Excluded 2:* If no to question 2, stop screening. ■ And so on.

how articles will be divided among the screeners, and software applications to be used. The *screening questions* are yes/no questions used to decide if a study described in an article will be included in the review. An example is shown in **TABLE 5.5** along with suggested labels. The number of screeners should be at least two per article, and each excluded article should be labeled with a reason for exclusion.[6] Although reasons are not required during the title/abstract phase according to most standards, many researchers choose to provide them. Note that during the title/abstract screening, screeners are looking for reasons to exclude an article, while during the full-text selection—screeners are ensuring that the study matches all of the eligibility criteria.

There are various options for software to use during screening—some reviewers choose to do the screening within a citation software (e.g., Endnote, RefWorks),[21,22] a spreadsheet, or a tool specifically designed to conduct screening such as Rayyan or abstrackr.[23,24,25,26]

Step 3b: Evaluating Screening

Authors should determine the procedure and should document the method of settling disagreements between screeners. Compare labels between authors, focusing especially on those where one screener labeled articles as "include," and the other labeled them as "exclude." The objective level of agreement between screening decisions can be calculated using Gwets ac1, a measure of inter-rater reliability.[27] Although this is not required by any standard, sometimes researchers choose to add this to review reports. Eventually, all citations need to be labeled as included or excluded, and at which stage they were excluded.

Step 3c: Appraise Methods of Articles

Appraisal of the included articles focuses on the studies' methods; it is recommended that two people assess each article. Appraisal checklists are freely available for a variety of study types including randomized controlled trials, cohort, case-control, survey, qualitative study, and others. Although the checklists will vary, all evaluate the suitability of the study design to the research question, correctness of the sampling, appropriateness of the exposure/outcome measures, and validity, reliability, and significance of the results.[28] Examples include the Cochrane Collaboration Risk of Bias Tool designed for randomized controlled trials and the Joanna Briggs Institute Critical Appraisal Tools covering case-control studies, cohort studies, randomized controlled trials, and more.[29,30]

Step 3d: Evaluation of Appraisal

Compare the appraisal answers for each article and resolve any disagreements. Document the procedure for the resolutions.

Step 4: Expanded Search Techniques (Part 2 of Search)

After screening the articles from the bibliographic database searches, a variety of expanded search strategies could be employed to ensure that all relevant articles have been located. The main reason for expanding the search beyond bibliographic databases is to minimize publication bias, which is the systematic tendency of commercial publishers to publish empirical research based on the nature and direction of the results.[31] Not all reviews will employ all of these strategies, but nearly all will include the citations search, and many will include some gray literature. All articles retrieved using any of these strategies will then go through the appraisal process.

Step 4a: Reference/Citation Searching

Create a list of all included articles, previous reviews, and highly related articles, and then browse the references of these articles and any articles that have cited them. There are three main resources for conducting these searches: Scopus, Web of Science, and Google Scholar. Each of these resources documents the resources citing each other, and each one indexes a different list of resources. Of the three, Scopus indexes the most journal titles, Web of Knowledge indexes the widest range of years, and Google Scholar includes a large amount of gray literature. Comparing the coverage of journal titles, Scopus indexes several more unique titles than the Web of Knowledge. The journal titles indexed by Google Scholar are not provided by Google.[32] While browsing the cited and citing articles, retrieve all citations that may be relevant, and put these through the same processes as those retrieved during the database searches.

Step 4b: Gray Literature Search

Gray literature refers to any publications not published or indexed by commercial publishing companies. This collection includes preprints, government reports, white papers, conference papers/presentations, patents, technical reports, dissertations, theses, trial registries, grants, websites, open access journals, and blogs. Each of these resources is indexed in varying degrees by databases that often present few search options and are inefficient and/or retrieve thousands of irrelevant results. **TABLE 5.6** is an abbreviated list of freely available gray literature databases.

Step 4c: Request Studies

Posting a request in places likely to be seen by researchers in a review's topic area is a useful strategy. Requests could be posted in listservs, blogs, and professional organization websites' discussion areas, or sent directly to a selected list of authors. This activity can generate a list of studies that were unpublished, are nearing publication, or are otherwise hidden.

Step 5: Code and Synthesize

Synthesizing the studies requires first coding data/characteristics from each study and then combining the information in appropriate ways. There are dozens of methods for synthesis, and a review may use several. The most often utilized approaches are described in the following sections.

TABLE 5.6 Gray Literature Databases

Overall gray literature	■ OpenGrey (http://www.opengrey.eu/) ■ WorldCat (http://www.worldcat.org/)
Government documents	■ Federal Digital System (https://www.gpo.gov/fdsys/) ■ National Technical Information Service (NTIS) (https://www.ntis.gov/)
Trial registries	■ Clinical Trials (https://clinicaltrials.gov/) ■ World Health Organization International Clinical Trials Registry Platform (http://www.who.int/ictrp/en/)

Step 5a: Coding

Coding, or data abstraction, involves creating a worksheet or form to complete for each study. The form is a tool to collect all important data needed to answer the research question and to conduct the appropriate synthesis type. Review authors may consult several good examples to get ideas for developing the codebook. The *Community Guide* and the *Cochrane Handbook* provide a list of potential data elements that should be included.[6,33] Data elements include study population characteristics, study design, details of the intervention(s), and measurements/outcomes. The codebook form is created in a variety of tools including review software, a database creator, or a spreadsheet. Google Forms is an option that is free, quick to use, and provides summaries of data in bar graphs and pie charts, as well as a spreadsheet.[34]

Step 5b: Qualitative Synthesis

Qualitative synthesis is conducted by nearly all systematic reviews, even those that plan to conduct a meta-analysis. The most common approach is a *narrative synthesis*, which combines results from different types of research by describing its scope and its strength, presented by text and tables. There are several potential uses for this approach: to develop, advance, or validate a theory; to examine relationships in the data; to describe and explain complex or contentious issues, and to highlight emerging topics. Other types of qualitative synthesis include *framework synthesis*, which compares results of collected research with a preselected framework, and *thematic synthesis*, which combines results from qualitative research into themes.[4]

Step 5c: Quantitative Synthesis (Meta-analysis)

A meta-analysis is a collection of statistical procedures that synthesize the "findings of studies that investigate the same research question using the same methods of measurement."[7(p153)] This technique results in calculating an average effect for the selected outcome across the studies, which need to have similar study designs and participants. The selected outcome or *effect size* may need to be standardized for a proper comparison. The process of standardization will depend on the type of variable, with the most common being the standardized mean difference, odds ratio, risk ratio, and correlation coefficient. Also, a weight is given to each study based on sample size and precision.[35] Next, the level of similarity is subjectively assessed and calculated by a *test for heterogeneity*. If the studies are found to be homogeneous, a *fixed effects analysis* is conducted. If the level of heterogeneity is not too high, a *random-effects analysis* is completed, which is a more conservative estimate, making it less likely to conclude that the intervention is effective when it is not. If studies are too heterogeneous, a meta-analysis cannot be conducted. The results of these analyses are presented in a *forest plot* (see **FIGURE 5.3**), which presents the *point estimate* of the outcome for each study (usually represented by a square) along with its *confidence interval (CI)* as a horizontal length of line and indication of the relative number of participants in the study by the size of the square. A vertical line called the *line of no effect* is added for a quick visual comparison. The calculated average effect size is represented by a diamond.[4]

Step 5d: Integrative Synthesis

Integrating both quantitative and qualitative studies into one synthesis can provide conclusions that highlight the strengths of both types of studies. Quantitative studies demonstrate evidence of effectiveness or size of relationships between variables, whereas qualitative studies reveal perspectives on appropriateness or acceptance, why/how interventions work, and contextual issues. Two mixed methods synthesis processes have been formalized and described. A *realist synthesis* works well with complex interventions by identifying when and how interventions work.[8] *Bayesian meta-analysis* is "a method of synthesis where a summary of qualitative data is used to develop a probability distribution (prior distribution), which can be tested later using a more conventional synthesis of quantitative data."[7(p157)] A *probability distribution* "shows how the total probability

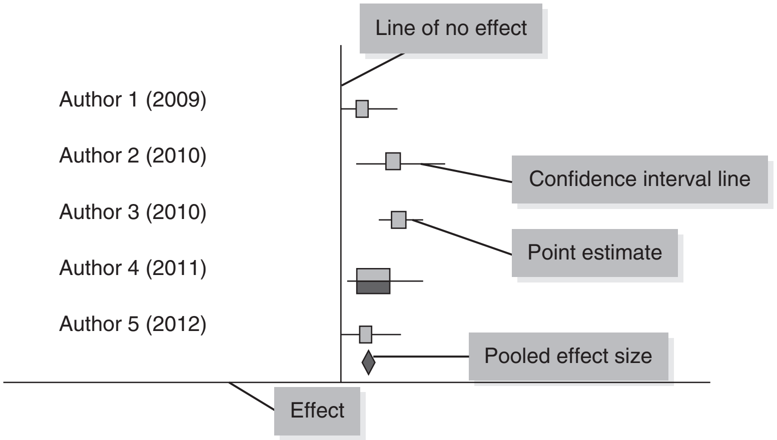


FIGURE 5.3 Example of a forest plot.

(which equals 1) is distributed among the different possible values of a variable."[36(p473)] Also, this analysis recognizes the value of subjective judgment within evidence-based practice and considers the views of prospective users of the review.

Step 6: Analyze and Write

The final step is to analyze the overall context of the evidence synthesis by summarizing the strength of the evidence and its generalizability, determining its limitations, providing recommendations for action, and writing the review in appropriate formats for the selected audience.

Step 6a: Analyze the Strength of the Evidence

The strength of the evidence can be described by scrutinizing the results of the synthesis from various perspectives. First, assess the generalizability of the synthesis and the level of representativeness for various populations and settings. Next, evaluate the weight given to studies in the synthesis, whether done explicitly or not, to ensure that those studies given the most weight were the right studies to do so. Then, examine the influence of outliers on effect size or of unusual contexts or settings on synthesis. Finally, consider views of stakeholders and any competing explanations.[7]

Step 6b: Assess Limitations

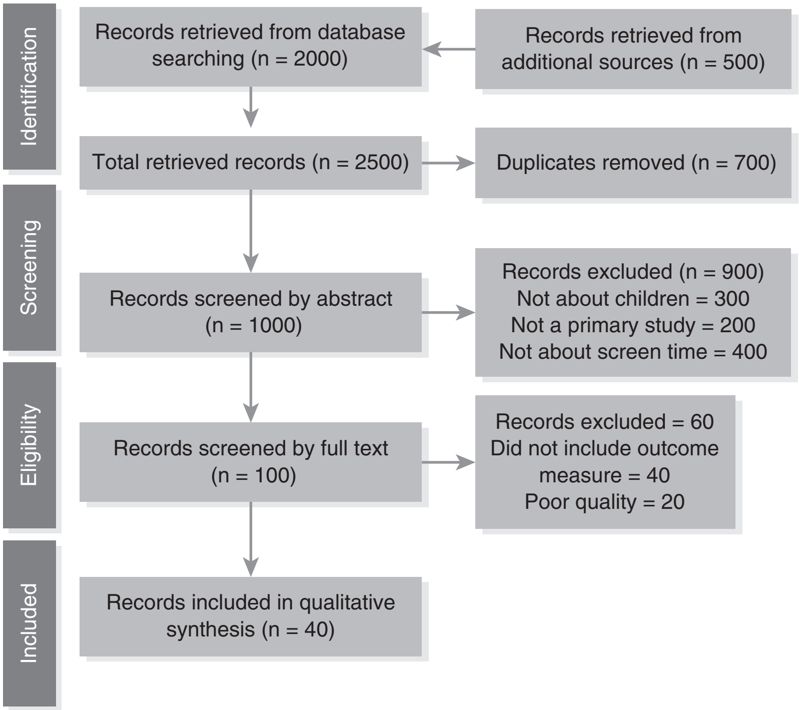
In determining limitations, authors should consider the potential gaps in the literature sample and describe potential publication bias and should acknowledge the risk of bias in the included studies. No matter how extensive the literature search, the sample could be missing relevant studies. Reporting bias, discussed in Step 4, is a collection of biases that has been well documented, showing "that it is more likely that significant positive findings will be published (publication bias), in a timely manner (time lag bias), in English (language bias), in multiple places (duplicate publication bias), cited more often (citation bias), and in journals that are widely indexed (location bias)."[37(p144)] Publication bias can be evaluated by a funnel plot.[31] The bias within the included study depends on the internal and external validity. In the analysis, detail the overall biases found in the literature, answering: How reliable are the studies? Do the outcomes in the studies vary due to quality? Are results influenced by one or two studies, without which the overall conclusions would change?[4]

Step 6c: List Recommendations for Action

Two types of recommendations are typically provided by systematic review authors: implications of the review's findings and recommendations for further research. Many journals request authors to include suggestions for practitioners; however, the *Cochrane Handbook* warns against listing these inferences, because the Cochrane Collaboration considers it to be outside of a systematic review's scope to provide these implications. The *Handbook* states that "the highest level of explicitness would involve a formal economic analysis with sensitivity analysis involving different assumptions about value and preferences."[6(p380)] If needed, recommended actions should be placed in the context of specific values, preferences, and settings explicitly found in the evidence. A list of potential future research should also be thoughtfully written. Some questions to consider are: Is a conceptual map or theoretical framework available for this topic? Is there a lack of representation of any population groups? Are all appropriate outcomes reported?[7]

Step 6d: Register Protocol and Write the Report

Authors should consider submitting the review to a protocol registry such as Prospero, Cochrane Collaboration, or Joanna Briggs Institute.[38,39,40] Some biomedical journals have started requiring that authors register the review before the final report can be published, while others strongly encourage authors to do so. In writing the formal review protocol or final report, use the PRISMA checklist to provide report elements and sequence, although some of the elements are not appropriate for all systematic reviews.[41] PRISMA also advises review authors to depict the flow of articles through the review process in a flowchart (see **FIGURE 5.4**). Most journals place limits on the number of words, tables, and figures that can be included, so authors must carefully select information to be reported, while



Identification
Screening
Eligibility
Included
Records retrieved from database searching (n = 2000)
Records retrieved from additional sources (n = 500)
Total retrieved records (n = 2500)
Duplicates removed (n = 700)
Records screened by abstract (n = 1000)
Records excluded (n = 900)
Not about children = 300
Not a primary study = 200
Not about screen time = 400
Records screened by full text (n = 100)
Records excluded = 60
Did not include outcome measure = 40
Poor quality = 20
Records included in qualitative synthesis (n = 40)

FIGURE 5.4 Example of a PRISMA flowchart.

Modified from Liberati A, Altman DG, Tetzlaff J, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: Explanation and elaboration. *BMJ*. 2009;339:b2700.

not being overly selective in a manner that limits reporting important outcomes and influences conclusions. In disseminating the review, it may be necessary to write in other formats for various audiences including patients, policymakers, media, research funders, practitioners, or the public in general.

Summary

Systematic reviews will continue to be the method of choice when synthesis of the literature is required. By summarizing and appraising primary studies, authors provide practitioners, policymakers, patients, and researchers with evidence-based answers. Authors should follow standards to minimize bias and deliver an effective synthesis. Findings should be distributed to appropriate stakeholders.

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CHAPTER 6

Methodology

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CHAPTER OVERVIEW

This chapter covers research design and methodology that become the methods section of a research project. Choosing the right design adds validity, reliability, and strength to the results and conclusions. The best of projects can be derailed by errors in experimental design and weakened by a poor choice of research design. Challenges to validity and reliability that may emerge at the peer-review stage must be considered when developing the methods for an investigation.

LEARNING OBJECTIVES

- Define research methodology.
- List the elements of methodology.
- Draw the schematic for selected research designs.
- List, define, and discuss the type of analysis for each research design.
- List and discuss the types of studies.
- Define, identify, and discuss the terms bias, error, reliability, validity, threats to validity, and types of data.

Introduction

Once the topic and specific research questions, or hypotheses, have been identified and the literature review has been completed, the investigator must choose a methodology suitable for achieving the project's objective. This objective is stated as a hypothesis, a purpose statement, or a clear and specific research question. Additionally, the primary objective should answer the following question: Is it important to medicine, the profession, or society? That is, will the study make a significant contribution to the field's body of knowledge? Some journals refer to this as the "so what?" question. In many cases, authors are required to respond in writing to this question when submitting a manuscript for publication. Answering this question helps the investigator condense the meaning and value of the study. This question should be a guiding principle for most research endeavors.

The research obejectives should drive the methodology. When choosing a methodology, two mistakes may distract novice investigators. The first mistake often made is selecting a familiar methodology without first defining the research objectives. The second most common mistake is planning to use already available data. Although convenient, this backward approach may produce trivial information that is unlikely to contribute to the field. The methodology should generate data that achieve worthwhile objectives.

The Methods Section

The methods section describes how the research study was conducted. It should be sufficiently clear and detailed so that others can duplicate the study. The methods section includes descriptions of the following:

- Subjects
- Instrumentation used (including questionnaires, when applicable)
- Procedures performed
- Analytic procedures used for evaluating and summarizing the data

Data analysis must be suited to the particulars of the study: the number of subject groups (e.g., two: an intervention and a control group), the number of subjects within each group, and the procedures used for data collection (e.g., single or repeated measures). Many healthcare researchers value a quantitative analytic approach using statistical methods. Although this is often the case, some questions in health care must be answered using a qualitative approach.

A Methods Scheme

Each study plan poses its challenges. A system such as the one presented in **TABLE 6.1** is a useful tool for identifying some study options. First, the researcher must decide whether the approach will be analytic

TABLE 6.1 Selected Research Designs

Name	Design	Statistical Test
One-shot case study	X O	None
One group pretest–posttest	O X O	Dependent or paired *t*-test Wilcoxson matched pairs, signed ranks
Static group comparison	X O O	Independent *t*-test Chi-squared Mann-Whitney *U*
Posttest-only control group	R X O R O	Independent *t*-test or ANOVA Mann-Whitney *U* Kruskal-Wallis ANOVA

Name	Design	Statistical Test
Nonequivalent control group	O X O O O	ANCOVA or ANOVA
Pretest–posttest control group	R O X O R O O	ANCOVA or ANOVA
Solomon four-group	R O X O R O O R X O R O	ANCOVA or ANOVA
Counterbalanced	X_1 O X_2 O X_3 O X_2 O X_3 O X_1 O X_3 O X_1 O X_2 O	ANOVA
Time series	O O O O X O O O O	ANOVA, trend analysis

X = experimental treatment or intervention; O = observation, measurement, or evaluation; R = randomization of a large number of subjects; ANOVA = analysis of variance; ANCOVA = analysis of covariance.

or descriptive by answering the question: Is there a comparison between groups in this study?

Understanding Research Design

Controlling Bias

When designing research, the investigator must limit or control factors and biases that could potentially contaminate a study. As mentioned in previous chapters, all research starts with an idea or a problem. The research hypothesis is the investigator's expectation for the outcome or the solution to the problem. The objective of a research study is to prove or disprove the investigator's hunch.

When selecting a research design, the investigator must consider the expectation (i.e., the research hypothesis) and create a means of controlling biases that may result from this expectation. In other words, an informed, objective observer must be able to conclude that the researcher's bias (or prior expectations) did not influence the results of the study. The investigator must design the research to eliminate bias, thus allowing the results of the study to represent the true effect of the independent variable.

Other reasons for understanding research design include recognizing and minimizing the effect of threats to validity, both internal and external. In this chapter, the concepts of error and reliability, forms of validity, and a method of identifying and diagramming typical research designs will be discussed.

Error

All research involves measurement, and all measurements involve error. The common formula for a given measurement is

$$\text{True measurement} = \text{Observed measurement} + \text{Error}$$

As the concept of "error" decreases, the observed measurement begins to approximate the true measurement. In everyday life, errors in measurement are common; for example, anyone who has ever tried to cut a shelf to put inside a closet may be painfully aware of the formula for an observed measurement. If the observed measurement includes too great of an error, then the shelf will be either too large or too small and will not fit in the closet. Therefore, the error term can be either positive (too large) or negative (too small).

Types of Error

Error can be categorized into two forms, random and systematic. Random error consists of those errors that occur strictly because of chance; these errors are often thought of as "noise in the system." Small sample sizes tend to be more vulnerable to random error. For example, if five measurements are taken versus one measurement, the average of the five measurements is less likely to be incorrect or have a large error term. The carpenter's proverb of "measure twice, cut once" affirms the role of random errors.

Systematic error can be thought of as a series of consistent biases affecting a measurement. Typical researcher errors may be related to poor technique, such as sloppiness, or to inappropriate research designs, inappropriate measures, or incorrect statistical applications. For example, if a researcher is using heart rate (beats per minute) as an indicator and calculates heart rate using 10-second readings in some cases and 15-second readings in others, then the error risk increases. The measuring technique introduces errors of inconsistency.

Similarly, if a researcher uses a survey to assess a clinical outcome, error may be introduced by several factors including differences in verbal fluency among subjects or even the conditions under which the survey is completed. For instance, consider the differences in response to a telephone survey about practitioner satisfaction by an individual who has just experienced a 2-hour traffic jam versus a responder who has just exercised and feels wonderful. Differences in their levels of stress may affect their responses.

By choosing appropriate measurements, using reliable techniques, and employing valid instruments to obtain measurements, a researcher can eliminate a substantial number of experimental errors in data collection. Reliability and validity are fundamental to obtaining appropriate and useful data.

Reliability

Reliability focuses on the consistency with which a measurement is taken. If a measurement lacks reliability, then the data obtained may be useless because of error. In other words, if substantial error exists in the measurements, then the researcher cannot know whether observed changes in the dependent variable are caused by manipulation of the independent variable or by poor measurement. Reliability is also of paramount importance to the professional in clinical practice. If a clinician does not gather reliable data, then there is no way of knowing whether apparent changes in the patient are the result of actual physiological changes or poor technique. In other words, the clinician will not know if progress is taking place as a result of treatment.

Forms of Reliability

There are three common forms of reliability: instrument reliability, intrarater reliability, and interrater reliability. Instrument reliability indicates the consistency of measurement by a particular instrument. For example, if a weighing scale has a worn spring, it may measure lighter weights accurately but heavier weights inaccurately. The method to improve instrument reliability is to calibrate the instrument consistently.

Intrarater reliability indicates the consistency with which an individual takes measurements. For example, does the healthcare provider measure blood pressure, in the same way, every time? If not, there is a strong possibility that the measurements will differ because of technique rather than differences in the patient. One method of improving intrarater reliability is to follow an established protocol consistently and to check for consistency routinely.

Interrater reliability indicates the consistency in measurements among individuals taking the measurements. If more than one individual is taking a measurement, there must be adequate assurances that any changes are caused by changes in the true measurement, rather than fluctuations in human error. The concept of interrater reliability is often ignored and has important ramifications for clinical research. Inattention to interrater reliability may obscure differences in the research outcome. If individuals collecting data do not perform the related tasks in the same way, the researchers will not be able to ascertain whether differences are caused by differences in the patient or differences in the way the measurement was performed (i.e., an error).

The "two P rule" (protocol and practice) applies when two or more individuals are taking measurements. Measurements should be taken using a standard protocol that has been practiced. Data collectors should also compare their measurements periodically; they may even wish to determine their consistency by performing one of the tests that assess interrater reliability, such as the kappa-statistic test. When reviewing an article that involves measurements, the reader should look for an assessment or other assurance that the data were gathered reliably.

Validity

Another concept that must be considered regarding data and measurement in an investigation is validity. Validity indicates the usefulness or appropriateness of the data being gathered. In a practical sense, reliability and validity are related concepts. Reliability focuses on consistency of measurement, whereas validity focuses on the appropriateness of a given measurement. A simple illustration is a game of darts. Reliability can be viewed as the consistency of the pattern or spread of the darts. Validity can be thought of as ensuring that the darts are aimed at a dartboard. There are two principal types of validity: measurement or test validity, and design or experimental validity.

Measurement or Test Validity

Measurement or test validity answers the question: Does the test or measure do what it is intended to do? For this to occur, a given measurement should have a defined purpose and should relate to a given phenomenon (e.g., a clinician routinely takes a temperature because this vital sign can be an indication of an inflammatory process). For this chapter, we will focus on some common forms of test validity.

The first form is face validity, which addresses the question: Does the particular measurement or method appear to be appropriate? This form of validity often relies on the opinion of experts. Most authorities consider face validity the weakest form of test and measurement validity. Another form is construct validity, which assesses the degree to which the measurement is based on theory. In the example of measuring body temperature, the construct that an inflammation involves heat provides modest construct validity. On the other hand, content validity asks whether the test is broad enough to address the scope of the content. For example, if students' knowledge of anatomy were being tested, but they were only tested on the anatomy of the upper extremity, then that particular test would lack content validity. Finally, criterion validity is an indication of how well the test performs and whether it is useful when judged against a standard. There are generally two subcategories of criterion validity: predictive validity and concurrent validity. Predictive validity assesses whether and how well a test predicts a specific phenomenon or outcome. For example, how well does a positive straight leg raise accurately predict a lumbar disc protrusion? Concurrent validity asks whether the test performs as well as an accepted test. Generally, this category is used to validate a short or noninvasive version of a test. For example, concurrent validity would be used to establish the validity of a urine test, as opposed to a serum glucose test, to monitor diabetes mellitus.

Design or Experimental Validity

There are two forms of design or experimental validity: internal and external. Internal validity is concerned with limiting or controlling factors and events other than the independent variable, which may cause changes in the outcome—dependent variable. These factors or events are known as threats to internal validity. External validity, on the other hand, is concerned with factors that may affect the generalizability of the conclusions drawn from the study. These factors are referred to as threats to external validity. The next section examines these two concepts.

Threats to Internal Validity

As mentioned, threats and concerns related to internal validity are unintended factors and conditions that can affect the results. For example, if an investigator is assessing the effects of two dietary regimens and does not take into account the subjects' levels of activity, then the internal validity of the study is threatened.

There are two broad categories of threats to internal validity: temporal or time-based effects, and measurement effects. Temporal or time-based effects consist of history, maturation, or attrition. History refers to effects on the dependent variable that are a result of the passage of time. For example, suppose an investigator is interested in a new topical ointment for the common cold sore caused by the herpes simplex virus. The researcher treats one group of patients with a new drug or topical ointment for 7 days and obtains excellent results. However, cold sores from the herpes simplex virus are thought to be self-limiting, with symptoms generally resolving in 7 days. Therefore, the passage of time has obscured the effect of the topical ointment.

The next temporal effect or threat to internal validity is maturation, which can be thought of as threats that happen by changes as a result of development. Suppose an individual suggests that a particular type of rehabilitative therapy improves the development of infants' motor skills. In this example, the individual contends that the therapy helps infants walk sooner. The effects of that therapy and potential changes in the infants' motor skills may not be the result of the type of therapy involved, but rather of the developmental process. Thus, the experiment may be flawed by threats to internal validity, specifically maturation.

The third temporal effect or threat to internal validity results from attrition. When subjects leave a study prematurely, the results may be distorted. Consider the consequences of a study involving a new drug for migraine headache sufferers. In this hypothetical study, one group of subjects receives the new drug, and their results are compared with another group of subjects who receive a placebo. The subjects will be seen every 3 weeks for 6 months. Suppose subjects taking the new drug no longer experience migraine headaches, so they no longer come to their appointments. The only participants left in the study are those for whom the drug did not work. Therefore, when comparing the placebo to the experimental drug after 6 months, there is no difference between the groups because the majority of participants who continue to have migraine headaches remained in the study. The subjects who were helped by the drug dropped out of the study, thereby affecting and possibly even distorting the results. Studies with a greater than 20% drop-out rate should be questioned.

Measurement effects are those threats to internal validity that result from an investigator trying to measure a phenomenon. The first threat is testing, especially when the test is repeated several times. Sometimes the actual act of performing a test on a patient affects the results of the study. Consider a hypothetical investigation in which the researcher is interested in the effect of a particular type of setting on function in individuals who have suffered a cerebral vascular accident. One of the measurements may be a functional test (e.g., how well the individual can dress without help from others). In this example, the investigator decides to administer a pretest to determine the baseline time needed for an individual to self-dress. In this case, having the patient get dressed may help the patient discover new and better strategies for getting dressed, thus contaminating the results. As a second example, consider an investigator who wishes to compare two forms of drug therapy on patients with cardiac problems. In this hypothetical study, the investigator chooses to use a step test (i.e., have the subjects step up and down repeatedly) and record the number of times subjects can continue until the heart rate reaches a predetermined maximum percentage. In this study, the patient's performance may be affected by the motor learning that takes place. In other words, the patient's coordination may improve just by completing the step test.

The next threat to internal validity is instrumentation. The type of instrumentation used may affect the results. Consider a study in which the investigator is interested in whether children with handwriting problems press their pencils harder on the paper. To measure the point pressure of the writing implement, the children are asked to use a pencil-type instrument containing a force transducer and a wire that leads to a recording device. The fact that the instrument represents an unnatural pencil may affect the results. Thus, the instrument itself is a threat to internal validity.

Another threat to internal validity is sampling. Sampling effects include the selection of subjects for a study according to some bias, whether recognized or not. If selected in a biased way, the subjects are not representative of the population. For example, if subjects were surveyed in a study via a questionnaire that was sent only to residents in an affluent suburb, then the conclusions drawn from the results may be affected by the sample that was surveyed.

The final measurement effect that represents a threat to internal validity is statistical regression to the mean. Simply stated, this is the tendency for a group of outliers to move toward the mean (the average), not necessarily because of any difference in the subjects' characteristics, but because of the laws of probability. A classic example of statistical regression to the mean can be illustrated by what happened when students with developmental and learning challenges were mainstreamed into a classroom with so-called "normal" students. After a period of time, they were tested and their scores on a developmental and learning inventory improved. The researchers then hypothesized that, if scores improved by putting challenged students in a "normal" class, then perhaps putting "normal" students in a class with gifted students would bring the "normal" students' aptitudes up. However, when the students in the class were retested, the exceptional students appeared to do worse on the test. Did the exposure to "normal" students somehow contaminate these learners? The answer is no. What happened was simply statistical regression to the mean. In both cases, the group that was being tested (the developmentally challenged and the gifted students) came from the ends of the distribution of test scores, that is, the highest and lowest scores. On the retest, their scores tended to migrate toward the mean or toward that typical score within a population. Therefore, investigations may be affected by statistical regression to the mean by utilizing subjects who may be considered outliers.

▸ Threats to External Validity

As previously mentioned, threats to external validity include factors and conditions that affect the ability to generalize the results of a study. Threats to external validity can be placed into two categories: threats related to the populations used and those related to the environment in which the study takes place (i.e., environmental threats).

Population-Related Threats to External Validity

The first population-related threat to external validity concerns the subjects' accessibility to the study. When one performs a study, one usually studies a portion of a given population—a sample. If the sample used in an experiment or investigation is substantially different from the population, then the ability to generalize the results to the population may be compromised. This threat may be of particular interest in clinical studies. In the majority of clinical studies, the subject generally has access to medical care and the ability to continue with treatment. Therefore, these subjects may not represent the entire population, which may include individuals who have compromised access to medical care.

The second threat to external validity in the population category is known as subject–treatment interaction. This threat can be described as the confounding effects of the subjects' attributes on the dependent variable. Because of genetic makeup, lifestyle, or other confounding variables, certain subjects react differently (i.e., either more positively or more negatively) to any given treatment. For example, some people are blessed with a metabolism that allows them to eat whatever they wish without gaining any weight. On the other hand, other people who follow the same diet may gain weight.

Environmental or Experiment-Related Threats to External Validity

One environmental or experiment-related threat to external validity is the description of the variables. If the variables used in a study are not described precisely and with sufficient detail, then it may be difficult for subsequent investigators to replicate the study or obtain the same results. For example, consider a new antihypertensive drug study where the control subjects receive "conventional therapy," but this is not specified in detail. A clinician may not be able to determine whether the new drug is preferable to current therapy if not enough detail is available to ascertain how similar the new drug therapy is to the control therapy. A second environmental threat takes place when there are multiple treatments involving test order. In some cases, when two treatments or two drugs are administered, one may potentiate the effects or affect the actions of the other. Failure to recognize the effect of treatment order or multiple treatments may hinder the practitioner's ability to apply the results of the study.

Named after a classic experiment by Elton Mayo, the Hawthorne effect is a threat to external validity. Mayo was looking at worker productivity at the Hawthorne Works plant located outside of Chicago. Mayo was interested in the effect of lighting on worker productivity. He explained to the workers that they would be in an experiment on productivity. Mayo then proceeded to increase the ambient lighting in the factory. As anticipated, productivity improved. In the next phase of his study, Mayo then dimmed the ambient lighting. Worker productivity increased again. Finally, Mayo raised the ambient lighting to the previous high-intensity level, and yet again productivity increased. Mayo concluded that the ambient lighting was unrelated to the workers' performance—rather, the fact that the workers knew they were being studied affected productivity. The Hawthorne effect is an effect on results caused by the subjects' knowing that they are participating in an experiment. Typically, subjects in clinical experiments have better compliance with treatment regimens than patients who are not participating in an experiment.

The Rosenthal effect refers to results caused by the involvement of the investigator in a study. The personal attributes, charisma, and abilities of the researcher can affect the results. For example, if an investigator is a charismatic practitioner, then patients may improve partially because of their belief in the clinician treating them. Other practitioners who attempt to obtain similar results are likely to be unsuccessful.

In every research study, the investigator must consider and try to control factors, conditions, and the effects of circumstances that threaten both internal and external validity. Similarly, professionals critically reading the literature must be aware of these threats to validity to determine the credibility of the conclusions and the applicability of the work in their practice. In many cases, the choice of research design affects the investigation's susceptibility to threats to validity.

Types of Studies

Descriptive Studies

Descriptive studies generate data that are either numerical or non-numerical. Non-numerical information may be presented as verbal commentaries about subjects' clinical characteristics and behaviors, histologic slides, radiologic images, and so on. For these data, descriptive methods from the subdiscipline of qualitative research are appropriate. For ethical and legal reasons, subjects' personal information must always be de-identified when qualitative findings are presented.

Similarly, numerical data on individual subjects are almost never presented in a research report. Numerical information is usually presented as statistical summaries such as averages and measures of variability. The mean, median, and mode are all measures of central tendency. The measure of variability most often used in medical literature is standard deviation. Occasionally, a range or standard error (SE, also called standard error of the mean, SEM) is used. When confidential information is not disclosed, numerical reports may be supported by exemplar, anecdotal, or model information that conveys valuable research or teaching lessons.

Analytic Studies

Analytic studies test for the following:

- Differences between groups (e.g., a group of patients receiving a drug compared to those receiving a placebo)
- Relationships among variables (e.g., the correlation between cholesterol levels and coronary artery occlusion)
- Both differences and relationships

A "true experiment" is a prospective design in which the researcher controls as many subject, treatment, and environmental variables as possible.

A cross-sectional study is a database of "snapshots" of subjects at one period. For example, childhood bone maturation may be studied by describing bone densities in a group of children ages 1, 3, 6, and 9 years old. A longitudinal approach would follow a group of 25 one-year-old children over the next 8 years. If the researcher could control all or most variables over time, then a longitudinal study could also be experimental. However, it would be difficult to determine whether intervening variables had corrupted the design. Therefore, long-term experiments involving human subjects are rare.

When there is substantial risk to human subjects, it is not always possible to conduct a true experiment ethically. The risk may be caused by inducing the disease or condition being studied or by testing an experimental intervention or treatment. As an alternative, it may be possible to study a disease (e.g., cervical cancer) by identifying those who already have it and those who do not and then comparing the two groups for factors that might have been responsible for the disease (e.g., human papillomavirus exposure). This type of study is known as a case-control study design.

Another experimental approach is to identify people who have or do not have a particular risk factor (e.g., human papillomavirus exposure) and then examine the two groups over time to identify those who develop the disease or condition. This type of study is known as a cohort study design. Whether a cohort or case-control study design is used, a control or reference group is necessary. For example, if a newscast reports all subjects in a group of individuals addicted to heroin have used marijuana, can we conclude that marijuana use leads to heroin addiction? If those addicted to heroin were found to have consumed whole milk, can we conclude that whole milk leads to heroin addiction? A control or reference group composed of people who do not use heroin is likely to show many have used marijuana or have consumed whole milk.

Prospective Versus Retrospective Designs

Data collection for prospective studies is planned in advance. Prospective designs include true experiments and concurrent cohort studies. The concurrent cohort design involves subjects who do not have the disease in question but have a suspected risk factor and are tested at a later time to determine whether the disease developed in them. In many cases, the prospective approach is the only way to obtain information about a new or recently discovered phenomenon, such as a previously unrecognized disorder or a newly developed technique.

True experiments attempt to gain strict control over the conditions of the study, including subject selection, instrument calibration, and the experimental environment. Compared to retrospective designs, prospective designs are credited with having better control of variables and a greater possibility of having valid and reliable standardized measurement methods. Disadvantages include cost (which may limit subject numbers) and the difficulty of extrapolating the results of strictly controlled methods to the clinical setting, where a similar level of control is not possible.

Retrospective studies examine data that already exist, including chart reviews and case-control studies. A retrospective approach may be the only ethical way to study the mechanisms of certain interventions. For example, thalidomide was widely prescribed outside the United States for nausea and vomiting during pregnancy, but later it was found to cause developmental defects. Looking back at the unexpected adverse events associated with a previously approved therapy is an example of a retrospective approach. In hindsight, the harms discovered provide valuable information that cannot be ethically studied prospectively.

It may be difficult to verify that retrospective data were collected properly when the researcher does not know exactly how and under what circumstances the data were collected. Collecting retrospective data is usually inexpensive, and data are available in large quantities. A large *N* value (the total number of participants in a study) may be used to compensate for variability. Therefore, the value and usefulness of a study should not be based solely on whether the data were collected prospectively or retrospectively. The particular method of data collection should be evaluated on its merit.

Uses of Statistics

Many skilled clinicians are skeptical or even fearful of statistics. They contend that "anything can be proved or disproved," and that readers are easily fooled. This is not true for those who know research methods and the basic statistical principles presented in this chapter. Statistical information is common in medical literature. A few easy-to-learn concepts enable clinicians to become informed consumers of medical information. This ability is invaluable for interpreting study results in journal articles, conference presentations, and drug advertisements. Because we rely on scientific information throughout our professional careers to understand new information, a healthcare provider should be familiar with clinical research methods and basic statistical terminology.

Statistics are used primarily in three ways in medical literature. First, statistics are used to describe and summarize group information. Second, they allow us to infer or generalize sample results to the larger population, which is essential because it is impossible or impractical to measure every individual. Third, statistics test for significant relationships or differences between groups of subjects.

Types of Data

A datum (singular of data) is a unit of information about a subject. An example would be the total cholesterol value of 178 mg/dL on a subject participating in a lipid study. Data may be nonnumerical (nominal or ordinal, also referred to as nonparametric because of the statistical tests that can be legitimately performed on these types of data) or numerical (interval or ratio, also called parametric).

Nominal data are characteristic names that have no numerical value; examples include male or female, black or white, osteoarthritis or rheumatoid arthritis, smoker or nonsmoker. Ordinal data have characteristics that are comparative and can be ordered by rank; examples are shorter or taller, less painful or more painful, darker or lighter, or an increased size of a palpable mass. Interval data have numerical values between units but no actual zero point; examples include degrees centigrade and blood glucose (i.e., a patient could not have a body temperature or blood glucose value of zero). Ratio data have numerical values between units, and a zero value is possible; examples include milligrams of alcohol per deciliter, basophils per cubic millimeter, and number of pack-years smoking history (number of packs smoked per day multiplied by the number of years smoked).

Like clinical data, numerical research data are preferred to non-numerical data. For instance, in a study on smokers, knowing the number of pack-years (numerical data) provides better information than knowing only that a patient smokes (non-numerical). The more powerful parametric statistical tests can be applied to numerical data.

Although it is not always possible to quantify data, data can be valuable in the descriptive, qualitative form. For example, a narrative about a radiograph of a hairline fracture with a detailed description of its important characteristics, landmarks, and possible origin may be more informative than just a report of a "hairline fracture: present or not present" on 100 films.

When it is not possible to use numerical data, nonparametric statistical tests (such as the Spearman's correlation or chi-squared) must be used. The application of parametric tests (e.g., Pearson's correlation or the *t*-test) to nonparametric data is a mistake because a falsely low *p*-value (probability value) is likely to be fabricated (i.e., referred to as an alpha or type I error). A falsely high *p*-value is likely to result when nonparametric tests are used for analyzing numerical (parametric) data. In this case, it is unlikely that a false hypothesis will be accepted, but consequentially a true one may be overlooked (i.e., a beta or type II error). This may occur when the calculated *p*-value is close to the desired alpha level.

These classifications of numerical data are commonly used in most scientific articles. However, qualitative research methods also serve invaluable roles in some medical studies and are used as extensively in clinical research as in clinical problem-solving.

Experimental Designs

An investigator must decide whether a qualitative or quantitative approach will more effectively address the research objective. A second decision is whether the study will involve retrospective data (e.g., clinical records) or prospective data (i.e., information that will be newly generated as part of the project). The implications of these decisions have been discussed earlier in this chapter.

If the investigator decides to use an experiment to answer the research question, then choosing the appropriate experimental design is imperative. In a project proposal, the investigator describes the methods to be used for analyzing the study's data. Many proposal guidelines suggest creating mock data that are likely to resemble the study's actual data. This process also helps the investigator plan for both computer needs and possibly consultation with a statistician or methodologist.

The selected research designs presented in Table 6.1 are likely to accommodate the needs of most investigators. Although experimental and epidemiological studies share some methodological similarities, epidemiologists have developed specialized techniques for the needs of their discipline. Some investigators may need to use advanced epidemiological techniques for their studies. In these cases, consulting an epidemiology textbook or an epidemiologist is appropriate. The statistical principles presented here apply to most experimental and epidemiological studies, whether prospective or retrospective. Familiarity with these principles should enable the clinician to converse knowledgeably with most clinical research methodologists and consultants.

Pre-Experimental, Experimental, and Quasi-Experimental Designs for Research

The purpose of this section is to provide the reader with a simple way to recognize common research designs and the associated threats to validity inherent in those designs. Most of the work conducted in this area can be attributed to Campbell and Stanley, who wrote the classic text *Experimental and Quasi-Experimental Designs for Research.*[1] They developed a shorthand method for diagramming research designs similar to the way English grammar has been classically taught—by diagramming sentences; students learn to understand proper grammar and sentence construction. Similarly, individuals can more easily recognize a research design by diagramming it.

Campbell and Stanley and others have used certain conventions. For this section, the following symbols are used:

- An R represents randomization and indicates a particular group was randomly selected or assigned.
- An M indicates the groups were matched.
- An X (with or without a subscript) indicates a treatment.
- An X_0 indicates no treatment or, in some cases, the control condition.
- An O indicates a measurement. If multiple measurements are taken, then subscripts, such as O_1, O_2, O_3, and so forth, may be used.
- A dashed line indicates nonequivalency and denotes the groups may be substantially different.

Pre-Experimental Designs

The pre-experimental designs are the weakest of the research designs and are subject to many threats to internal and external validity. They are characterized by the lack of a control group, sensitivity to temporal threats to internal validity, and poor generalizability.

One-Shot Case Study

The first pre-experimental design, the one-shot case study, is diagrammed as follows:

XO

In this design, a treatment is given, and a measurement is made. This particular design is typical of survey research. A group of respondents is identified based on one or more pre-existing criteria and are administered a questionnaire that is then measured. Another example of the one-shot case study is the typical high school or college classroom. The instructor assumes the students have a certain level of baseline knowledge when they enter the class, but this baseline is not measured. The treatment consists of the exposure in the class, and the measurement is the students' performance in the class. If the students do well, then the instructor may conclude it is because the students learned a great deal from the class. However, the instructor cannot justifiably arrive at that conclusion because the students' prior level of knowledge in the subject is unknown. This demonstrates how the one-shot case study is a weak design because of its vulnerability to threats to both internal and external validity.

Even with its limitations, the one-shot case study is useful for certain types of research, such as descriptive studies in which the investigator wishes to describe what currently exists. For example, most surveys can be characterized as one-shot case studies. Often the data they yield are very useful to clinicians and, therefore, are published in the medical literature. For example, Levine was interested in the clinical practice of lung transplantation and wanted to ascertain if there were wide differences among transplantation programs.[2] To describe the state of clinical practice, he surveyed 65 active lung transplantation programs. By requesting information on key areas of practice, such as lung preservation and posttransplantation care, he was able to conclude that there was substantial consensus and little variance among transplantation centers. The results could not be generalized to centers that did not respond. Also, these studies do not have a long "shelf life" because a survey is most often a snapshot of a phenomenon at a specific time. However, the information could be considered valuable because lung transplantation centers may be able to determine if the practices at their center are consistent with those at other centers.

One Group Pretest-Posttest

Slightly more robust is the one group pretest-posttest design. In this particular design, subjects receive a pretest, the treatment, and a posttest or retest:

OXO

This design is characteristic of clinical practice in which a patient (or a group of patients) is evaluated and diagnosed, a treatment is administered, and the patient (or a group) is then subsequently re-evaluated.

For example, a group of high school students is provided with education about alcohol abuse. The pretest and posttest may be a questionnaire on alcohol use. This design is particularly vulnerable to the temporal threats to internal validity, and therefore the investigator theoretically cannot conclude the outcome was the result of treatment because the illness may have been self-limiting or the subject may simply have outgrown the problem as a result of development. In the case of high school students, changes in alcohol use may be related to the time of year and lack of parties where alcohol is served rather than to alcohol abuse education.

Without the ability to compare the study group to a reference or control group, the effects of temporal threats to internal validity cannot be evaluated. Similarly, the results cannot be generalized because it is not known whether the patient (or group) is representative.

In a study on the effects of a 5-day immersion leadership development experience on current and aspiring nursing leaders, Tourangeau et al. assessed and compared self-appraisals by participants and assessments by colleagues before and 3 months after the experience.[3] Although they concluded "a concentrated leadership experience is effective in strengthening leadership behaviors," critical readers may point out several issues that challenge their conclusions. Because participants' colleagues assessed leadership behaviors before the experience and knew they would be completing another assessment later, they may have become more sensitive to observing leadership behaviors. In other words, some of the observed differences may be due to changes in the raters rather than in the participants. The study could have addressed the concern about differences in the raters by having them also rate individuals who did not undergo the leadership program. Ideally, the raters would have been blind to the subjects' participation, or in other words, they would not know whether a person they were rating had or had not participated in the leadership development program. If changes in leadership were observed for individuals who had not participated in the program, then at least some of the observed change could be attributed to the changes in the raters. This concern about the raters is further supported by the fact that the participants' self-report on leadership behaviors was not significantly different after the program. Finally, because the subjects were volunteers, those who felt they would benefit from the program may have self-selected to participate. Hence the subjects may not have been representative of aspiring nurse leaders.

Static Group Comparison

The third pre-experimental research design is entitled the static group comparison. In this design, a group that has received a treatment, or been exposed to a condition, is compared to a group that did not receive the treatment or was not exposed to the condition:

XO
_ _ _ _ _ _ _ _
O

The dashed line indicates that these groups are not equivalent. This design, which attempts some form of control with the group that was not treated or exposed, is better than the previous designs. However, because the groups were not randomly assigned, it cannot be concluded that they are equivalent.

This design is commonly used in environmental or occupational epidemiological studies. For example, one may be interested in a group of people who are living in an area that might be contaminated with a carcinogenic agent. The investigator may hypothesize that living in this area may result in a greater incidence of certain types of cancers. People who live in the contaminated area are compared with similar people who live in an uncontaminated area. If there is a greater and statistically significant difference in the number of people with cancer in the contaminated area, then the researcher could conclude the suspected carcinogen might be related. Please note that one cannot conclude causality from this type of design. Correlation and causation are different concepts. Correlation helps to identify a relationship between variables and the direction of that relationship.

The usefulness of the static group comparison is that it allows the study of variables that generally cannot be manipulated by the investigator. Legally and ethically, an investigator cannot require people to live in an area that is suspected to cause a disease or disability. On the other hand, if individuals choose to live in that area, then one can measure and analyze the effects and compare them to a similar group of individuals who live in a different "control" area.

An example of a static group comparison from the medical literature is a study by Lynch et al. that compared residency choices by medical students who did or did not participate in an optional rural health awareness program.[4] One group of medical students participated in an enrichment initiative entitled the Rural Health Scholars Program (RHSP), which included both didactic and experiential learning focusing on practice in underserved and rural areas. The proportion of participants that chose residencies in primary care, family medicine, community hospitals, and known underserved areas were compared to their classmates who did not participate in the RHSP. Although the results demonstrated that significantly more students who participated in the RHSP chose residencies in family medicine and community hospitals, the authors could not conclude that the RHSP was the "cause." Because the groups were nonequivalent, the possibility that medical students self-selected participation in the RHSP because of a possible interest in a rural primary care setting could not be ruled out.

In summary, one of the major problems with a static group comparison occurs because the groups are nonequivalent. Therefore, there is always the possibility that some factor other than the treatment is causing the results.

Experimental Designs

The next series of research designs are the true experimental designs. These studies are characterized by randomization of the subjects and a control group. Randomization does not mean the groups are identical. Randomization works on the law of probability, which suggests that when a group is selected or subjects are assigned randomly, the traits, characteristics, and conditions that may affect the outcome (confounding variables) are distributed roughly equally among the groups, thus canceling out their effect.

Pretest, Posttest, Control Group Design

The first experimental design includes a pretest, posttest, and control group. In this design, subjects are randomly assigned to a group, pretested, given a treatment or not given a treatment, and then tested after exposure to the treatment or no treatment:

$$\begin{array}{l} R\ O_1\ X_0\ O_2 \\ R\ O_1\ X_1\ O_2 \end{array}$$

In this diagram, two groups are compared on a single variable with two conditions (X_0 and X_1), but more than two groups or conditions can be analyzed using this design. Also, it is possible to examine more than one variable.

The pretest, posttest, control group design effectively rules out most threats to internal and external validity. Because it is the most rigorous design, the pretest, posttest, control group design is commonly accepted as the "gold standard" and is typically used in randomized clinical trials. It should be noted that in clinical trials and other research involving human subjects, it is unethical and often illegal to withhold treatment. Thus the control group may be the group that receives the conventional treatment while the experimental group receives the new treatment. In other words, the conventional treatment is sometimes used as a control or the baseline.

In a study to examine whether fortified cereals increased subjects' blood levels of selected B vitamins, Tucker et al. compared two groups of older adults—one who ate a fortified cereal and one who ate a cereal that was not fortified.[5] Their approach was to measure blood levels of homocysteine (an amino acid), folic acid, vitamin B_6, and vitamin B_{12} in subjects on two occasions to obtain baselines. According to the authors, "High homocysteine and low vitamin B concentrations have been linked to the risk of vascular disease, stroke, and dementia."[5(p805)] After obtaining baseline measures, the subjects were randomly assigned to a group that ate either a cup of fortified cereal daily or a cup of cereal that was not fortified. At 12 and 14 weeks the blood levels of homocysteine, folic acid, B_6, and B_{12} were measured[†].

Neither the subjects nor the investigators performing the tests knew whether a subject was consuming fortified cereal or not. When the group membership is unknown to the subject and the investigator (until the tests are concluded), the study is called a double-blind study. Both the subject and the investigator are "blind" to the treatment. Comparisons between the two groups revealed significant differences between them. Homocysteine levels were lower, whereas folic acid, B_6, and B_{12} levels were higher in the group that ate the fortified cereal. Because of the rigorous design of the study, the authors concluded that eating a fortified cereal benefits older adults.[6] Because major threats to internal and external validity were controlled, the observed differences were due to the treatment. Therefore, the results may be generalized to similar groups of individuals; that is, eating a cereal fortified with B vitamins benefits older adults.

Posttest-Only Control Group Design

The second experimental design is termed the posttest-only control group design. The subjects are randomized, given a treatment, and then the results are measured and compared:

$$\begin{matrix} R\ X_0\ O \\ R\ X_1\ O \end{matrix}$$

Typically, this type of design is used when a pretest is inappropriate or unavailable for other reasons. For example, an orthopedic group may be interested in the outcomes of a total hip replacement when using one particular appliance versus a second appliance. In this case, a pretest is inappropriate because patients who require total hip replacements lack substantial range of motion at the hip joint, often because of pain. In this example, the outcomes such as time to ambulation, pain, and range of motion may be appropriate to measure after the surgery. Because it is impossible to know the baseline or the pretest condition of the individuals, there might be some threats to internal validity based on preexisting conditions. However, randomization minimizes these effects.

Gallo and Staskin investigated the effect of external cues on patient compliance in performing pelvic-floor exercises.[6] Because compliance is measured after a patient is educated about a treatment program, a pretest was not appropriate. In this study, 86 women with stress urinary incontinence were given a program on pelvic-floor exercises and then were randomly assigned to a group that either received an additional audio cassette or did not. They were subsequently evaluated for compliance to the pelvic-floor exercise program, and the results were compared. The women who received the audio cassette labeled an external cue

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[†] The astute reader will undoubtedly observe that the example used is a slight variation from the classical pretest, posttest, control group design because the investigators used two baseline measurements and two posttest measurements, so the design was:

$$\begin{matrix} R\ O_1\ O_2\ X_{\text{not fortified}}\ O_3\ O_4 \\ R\ O_1\ O_2\ X_{\text{fortified}}\ O_3\ O_4 \end{matrix}$$

Ordinarily one might also be concerned about pretest-posttest sensitization with multiple tests, but in this study, the dependent variable was blood levels of homocysteine, B_6, B_{12}, and folic acid, which should not be affected by repeated testing.

by the authors, demonstrated significantly better compliance than the group who received only instruction.[6] In this case, the robust experimental design, a posttest-only control group design, controlled major threats to internal and external validity, allowing the authors to conclude that external cues improve compliance for women with stress urinary incontinence.

Solomon Four-Group Design

The next experimental design is the Solomon four-group design. In this design, groups with and without pretests are exposed to one of two treatments and are subsequently tested after treatment:

$$R\ O_1\ X_0\ O_2$$
$$R\ O_1\ X_1\ O_2$$
$$R\ X_0\ O_2$$
$$R\ X_1\ O_2$$

The Solomon four-group design is a combination of the previous two designs: the pretest, posttest, control group design and the posttest-only control group design. This particular design is useful because it allows an investigator to assess whether an effect occurs because of the pretest. On the other hand, this design requires twice as many subjects.

Danley et al. investigated the effect of a multimedia learning experience designed to prepare dental students and dentists to recognize and respond to domestic violence.[7] The investigators were interested in ensuring that observed changes in the subjects between the pretest and the posttest were not because the subjects completed the pretest. When the subjects who completed the pretest, the multimedia learning experience, and the posttest were compared to subjects who completed the multimedia learning experience and the posttest, but no pretest, investigators found no significant differences between the groups. On the other hand, the two groups who completed the multimedia learning experience were more knowledgeable than the subjects in the control group.[6]

Quasi-Experimental Designs

The final group of research designs is termed quasi-experimental designs. Although they are more rigorous than the pre-experimental designs, they are not as rigorous or as robust as the true experimental designs. Typically, they lack one or more of the characteristics that would make them true experimental designs. Generally, randomization or multiple measurements are lacking, thereby making testing effects a potential problem.

Nonequivalent Control Group Design

The nonequivalent control group design is similar to the pretest, posttest, control group design, but because the groups are not randomized they must be considered nonequivalent:

$$O_1\ X_0\ O_2$$
$$O_1\ X_1\ O_2$$

An example of the use of this design is a hypothetical comparison of patient satisfaction with care from two clinics: one clinic hired a clinician 6 months previously (X_1), and one clinic had no clinician (X_0). Many ways in which the patients differ might affect the outcome, such as age, years seen by the provider, and so forth. Because the groups are nonequivalent, the results obtained from studies using this particular design must be viewed with caution; pre-existing conditions in the subjects may account for the changes after treatment.

Kristjansson et al. studied the effectiveness of a short-duration learning experience for teenagers that focused on preventing skin cancer.[8] Because the presentation was given in a classroom, they compared the classes that received the presentation to classes that did not. In this example, randomly assigning students would have made the study very complex and unmanageable. Although their results suggested the short-duration learning experience was successful, the fact that the groups were nonequivalent suggests that they should be viewed with caution. For instance, it is not known if one or more classes were composed of students who were more concerned about their health or more motivated to accept the content presented.

Separate Sample Pretest, Posttest Design

The separate sample pretest, posttest design is used when the investigators suspect that the pretest will significantly bias the posttest results:

$$\begin{array}{c} O\ X \\ \text{– – – – – – – –} \\ X\ O \end{array}$$

Although measuring a change from pretest to posttest is appropriate when using a physical test such as blood level or heart rate, a pretest of a mental, psychological, or performance variable often affects the posttest. For example, a pretest for manual dexterity may result in some motor learning that could affect subsequent performance. If the investigators were interested in evaluating the effect of a new treatment, the observed changes could be due to motor learning from the pretest. The separate sample pretest, posttest design addresses concerns about the pretest biasing the outcome.

Markert et al. used a separate pretest, posttest design to assess the knowledge acquired by professionals who attended continuing medical education (CME) programs.[9] The investigators noted in this article that pretesting and posttesting attendees was an inappropriate approach for assessing knowledge. They felt that a pretest would bias performance on a posttest. Given the observation that most medical professionals are bright individuals who are committed to learning, it seems logical that they would remember items from a pretest. Instead, Markert et al. randomly assigned attendees to either a pretest group, which they considered a "control" group, or a posttest-only group, which they considered the "treatment" group. Upon comparing the groups, the treatment group demonstrated significantly more knowledge in selected topic areas.[9]

Time Series Design

A third quasi-experimental design is the time series design. In these designs, groups are compared to each other, and there are multiple tests:

$$\begin{array}{c} O_1\ X_0\ O_2\ O_3\ O_4 \\ O_1\ X_1\ O_2\ O_3\ O_4 \end{array}$$

Because there are multiple measurements, one cannot conclude that changes or differences are not a result of sensitization or learning. In other words, the threat to validity of repeated testing is of concern, as well as the threat that groups may be nonequivalent.

In a study that compared nursing and medical interventions for skin care, Pokorny et al. examined differences in patients who developed pressure sores and those who did not.[10] Data were gathered on the day of admission, the day of surgery, and the following 4 days. Because the patients were admitted for cardiac surgery, it was anticipated a subject would average 6 days in the hospital. The investigators in this study looked for differences in the daily nursing and medical interventions between patients who developed pressure sores and those who did not. For this study, the dependent variable (what was measured) consisted of the documented interventions, specifically differences. The authors concluded that multiple assessments of skin condition by nurses were important in preventing pressure sores.[10] Because patients were not randomly assigned to groups that received standard or optimized skin assessment, differences in patients may have affected the results.

Summary

The designs presented are by no means exhaustive of the pre-experimental, experimental, and quasi-experimental designs found in the literature. By recognizing the common designs, one can quickly focus on threats to validity. When designing a study, knowledge of common research designs may help avoid pitfalls. Although one can have a robust research design, failure to obtain reliable measurements using a valid instrument may render the conclusions of the study inaccurate or erroneous. Finally, reading research critically or performing research is a learning experience that generally requires a great deal of practice.

When evaluating the methods section of published research reports, this information should help clinicians to knowledgeably critique the methods used and evaluate the study's results before applying them to practice. For all clinicians, this information should help in interpreting new medical information presented in literature, professional conferences, and through other sources. Well-informed clinicians may be able to interpret and apply clinical information in new or better ways.

By definition, original research studies are unique. Applying the principles presented in this chapter should help beginning investigators select an effective research method for a planned research study and, when necessary, communicate effectively with methodological consultants.

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CHAPTER 7

Survey Research

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CHAPTER OVERVIEW

Surveys are one of the most commonly used methods to gather information and data in the world. Surveys are used to gather information as important as the U.S. Census or whom we plan to vote for in the next election or as mundane as the type of dishwashing soap we use or our favorite movie. Surveys can reveal trends, attitudes, opinions, lifestyles, needs, expectations, knowledge/information, behaviors, demographics—the list of uses is infinite. Surveys can be used in almost every aspect of our lives, and health care is no exception. A large amount of data from any number of people on a wide variety of subjects and issues can be gathered using surveys. Several formats are used to deliver and conduct surveys; they can be long or short; simple or complex. Surveys can use words, symbols, written responses, and simple or complex choices, and can collect quantitative or qualitative data. Despite its somewhat eclectic nature, survey research must still conform to the exacting requirements of design and methodology to have true value, meaning, and impact.

This chapter presents the basic concepts of survey research, including design, item construction, data analysis, and conducting the research. Emphasis is placed on designing items and developing concepts that are valid to survey research in health care. A short discussion of sample size is presented. The use of surveys in research and practice environments will be included.

LEARNING OBJECTIVES

- Discuss and evaluate the purpose of surveys.
- List the advantages and disadvantages of surveys.
- List the various types of surveys.
- Define verbal frequency scales and develop a verbal frequency scale.
- Develop survey items.
- Construct a survey.
- Discuss and identify survey analysis procedures.

What Surveys Can and Cannot Do

Surveys are used to gather many types of information: information on demographics, opinions, preferences, expectations, knowledge, and outcomes. Surveys can be conducted by mail (including email), in person, via telephone, and through the Internet. Survey samples can be very specific for selected individuals, less specific for groups of individuals, or more general for large populations. Sample subjects can be defined by almost any characteristic. Samples can be randomized or assigned, stratified or open, well defined, or ill-defined, or a sample of convenience. As shown in **TABLE 7.1**, surveys have several advantages for data collection; they can be a relatively easy, inexpensive, fast, and consistent research tool.

As shown in **TABLE 7.2**, surveys also have disadvantages. One major disadvantage is difficulty in establishing causality.[1] Causality involves manipulating a variable and determining the effect on another variable. This relationship is very difficult to establish using a one-time survey. However, well-designed surveys can be effectively used as preintervention and postintervention assessment tools in experimental and quasi-experimental designs.

TABLE 7.1 Some General Advantages of Surveys

Advantage	Reason
Costs	Relatively low cost, but depends on survey and methodology
Sample size	Can vary from small to extremely large; can be targeted
Issues	Can gather information on single or multiple issues or topics
Format	Can vary: mail, Internet, interview, telephone
Impact	Can yield very influential results

TABLE 7.2 Some General Disadvantages of Surveys

Disadvantage	Reason
Respondent self-report	There is no way to ensure individuals will respond to surveys or choose to participate.
Respondent interpretation	There is a risk that respondents will interpret survey items in a manner different from investigator intent.
Respondent bias	There is a risk that people who choose to respond may be different from the population being studied.
Extrapolation to non-responders	Can the response of a few be extrapolated to the population? Can the data be generalized?
Item bias	Is there bias in the way an item is worded (by the investigator) or interpreted (by respondents)?

Challenges associated with survey research revolve around the reliability of respondent self-reporting, respondent interpretation of survey items, extrapolation of results to a population, non-respondent influence, and respondent bias. Although these challenges to survey research cannot be completely avoided, good design and item construction should and will help to limit the impact and influence such issues have on outcomes.

Types of Surveys

As shown in **TABLE 7.3**, surveys are delivered in different formats. The choice of delivery format (distribution) is part of the methodology and

TABLE 7.3 Comparison of Survey Methods

Characteristic	Mail	Telephone	Interview	Internet
Cost	Moderate, depends on sample size	Low to moderate, depends on local versus long distance costs	Relatively high	Low, least expensive
Cost examples	Printing, postage, paper, envelopes	Telephone costs, personnel training, and expense to conduct an interview	Personnel training and expense to conduct an interview	Professional help with Web design
Response rate	Potentially low	Dependent on the willingness of subjects to participate	Relatively high; only willing subjects are interviewed	Variable, but instant; respondents must have Internet access
Investigator time	Relatively limited	Requires training of interviewers and/or time to conduct interviews	Requires training of interviewers and/or time to conduct interviews	Relatively limited
Respondent time	Completed as convenient	Telephone time	Interview time	Completed as convenient
Study time	Relatively long; must allow for mail and response times	Relatively short, but subject contact time may be long	Relatively short, but subject contact time may be long	Relatively short, dependent on subject time to respond
Anonymity	Survey form can be completely anonymous	Phone number is known	Person-to-person interaction	Web address can be identified
Sample size	Can be very large	Usually small to medium	Limited, usually small	Can be very large
Respondent bias	Respondent item interpretation	Interviewer voice influence	Interviewer influence is high	Must be computer literate
Investigator bias	Very limited except for item construction	Voice influence; interpretation of survey items	Influence of voice, facial expression, body movement; interpretation of survey items	Very limited except for item construction

(*continues*)

TABLE 7.3 Comparison of Survey Methods (*continued*)

Characteristic	Mail	Telephone	Interview	Internet
Other	Requires mailing lists	Multiple interviewers conducting a survey	Multiple interviewers conducting a survey	Computer access required

research design. Each format has advantages and disadvantages. The research purpose(s), study population, and sample size are factors that must be considered in the decision on the survey delivery. Surveys can be conducted by mail, telephone, Internet, and interview.

Most of this chapter will concentrate on Web-based surveys and those delivered by mail. The construction of the survey itself is very similar for both formats. Many Web-based surveys and paper surveys are delivered by email. Internet surveys have become the standard format for surveys. Telephone and interview surveys are briefly discussed.

Planning Is Key

Performing a survey investigation or study is more than thinking up some questions, putting them on paper or online. The meticulous planning required is as important for surveys as for any other type of research effort. One of the first steps is to define what is to be achieved in the study. Not much can be accomplished beyond a literature review until the study goals are conceptualized and what is to be achieved and learned are defined. The survey must have specific goals or objectives or aims that can be researched. Once the goals, objectives, and/or aims of the investigation are defined, everything that follows will reflect the research effort. This planning generates the research questions, hypotheses, or null hypotheses.

Response Rates

Response rates are a threat to any survey. Response rates tend to be low, particularly when used without a well-defined target population or sample.

Here are some helpful guidelines for surveys of health professionals, students, and educators.

- An introductory statement (cover letter if using regular mail) should accompany the survey. A personal salutation should be used if the subject is known to the investigator. Otherwise, Mr., Ms., Mrs., or a professional title such as Dr. should be used.
- The survey instrument must have well-designed content (items) and be visually appealing.
- A respondent should be able to complete the survey in a short period. The longer it takes to complete the survey, the less likely that it will be completed.
- Some inducement or gift may be included. However, this adds to the study expense, and there is no guarantee the response rate will be increased.[1]
- A follow-up request may spur some respondents. An email reminder may suffice.

Regarding the form and format of an email survey, these additional suggestions may be helpful.

- Begin with interesting questions (items).
- Use graphics and various question-writing techniques to ease the task of reading and answering the questions (simple is good).
- Use capital or dark letters for readability.
- Limit the length of the survey.
- Send notices and reminders at carefully spaced times.
    - Notice by email that a survey is coming
    - Email with the survey attached
    - A reminder
    - A second reminder (optional)

- If an identifier is used, explain that it is for recordkeeping only and that the respondent's confidentiality is protected. Respondent anonymity may be a key to response rates.

Much literature on survey research is available. A literature or Web search or book on survey research will help to develop and guide the survey research skills of the investigator.

Survey Introduction

The introductory information is presented at the beginning (obviously) of the survey. The survey introduction to a subject (respondent) is accomplished in two ways. The introduction, of course, depends on which survey format is used. For paper or Internet surveys, the introductory information is the first thing the subject should see. If a survey is sent by email with an attachment or a Web URL, the introductory information can be in the body of the email. For telephone or face-to-face delivery, the introductory information is read or provided in some physical way such as an agreement to participate. (For telephone surveys, the subject should voice his or her agreement to participate.) Regardless of the manner of introduction, certain basic points must be included. A well-worded, informative introduction helps to increase the response rate. If the subject understands the purpose and need for their input or information, they are more likely to respond.[1]

The key points for an effective introduction are summarized in **TABLES 7.4** and **7.5**. A well-defined and informative introduction may induce subjects to participate by appealing to their sense

TABLE 7.4 Key Points for the Introductory Statement or Cover Letter

Key Point	**Example**
Who you are	Describe yourself and/or organization and/or business in the opening paragraph
Background for study	In our practice, we have been using an appointment system . . .
Purpose of the study	We want to learn . . .
What will be done with the data	The information you provide will help us to . . .
Why they were chosen	We are asking you to take part because . . .
Assurance of confidentiality	You do not have to identify yourself in any way. All information will be reported in aggregate. All responses will be coded for study purposes.
What respondents need to do	Please take a few minutes to complete the survey. Please follow the instructions for each question.
The person respondents can contact if they have questions	If you have any questions or concerns, please contact . . .
Approvals for the survey, if applicable	This study has been approved by the Institutional Review Board of . . .

(*continues*)

TABLE 7.4 Key Points for the Introductory Statement or Cover Letter (*continued*)

Key Point	Example
Return deadlines	If possible, please complete and submit the survey by . . .
Statement of importance	The information you provide will be helpful in determining . . .
Acknowledge support	This study is supported by a grant from . . . This study is being conducted for ABC, Inc.
Statement of appreciation	We greatly appreciate your help in this matter and for taking the time to . . .
Closing	Sincerely, Your name, degree, titles
Signature	Co-investigators, degree, title

of responsibility and the importance of their information and input. The introduction statement should be concise, well written, informative, and easy to understand, as exemplified in **EXHIBIT 7.1**. The level of wording, grammar, and writing style should fit the subjects to be surveyed. Unless you are dealing with highly educated professional people, the introduction statement (like newspapers)

TABLE 7.5 Construction of a Hard Copy Cover Letter

Construction Point	Explanation
Limit to one page.	The longer the letter is, the less likely it is to be read completely.
Use common block format with a readable font (e.g., Times New Roman, font size 12).	Script, serif, calligraphy, and the like are hard to read.
White, beige, or light gray paper, black print	Easy to read; visually pleasing.
Common language.	Readability and ease of understanding are key.

EXHIBIT 7.1 Example of an Introductory Statement from the Author's Research

Dear <Participant>,

I invite you to participate in a survey on the importance of ranking health professions programs. You may access this survey by clicking on the URL below. You were selected to participate in this investigation by random selection from your professional organization's membership list. You do not have to identify yourself in any manner. Results will be reported in aggregate form. This is the first investigation on the opinion of health professionals on the ranking of educational programs. Your input will guide us in recommendations to the public and organizations. This investigation was approved as exempt by the IRB of State University. Please contact me at the address below if you have any questions.

Thank you,
J. D. Blessing

should target an audience with middle school reading ability.

Proofreading and editing are essential. It is a good idea to have individuals who are not part of the investigation read and interpret the introduction. An investigator may choose individuals who are representative of the subject sample or population to review the introduction and provide feedback. For either choice, include the introductory statement in any pre-study evaluations or pretests of the survey instrument and pilot studies.

Follow-Up

Follow-up notices or reminders to complete and return surveys may help increase response rates. Use a follow-up email, letter, or postcard. Be aware of reminders for surveys that deal with sensitive or very private information. For example, an investigator is studying the rate of sexually transmitted diseases (STDs) in corporate executives who travel frequently. Any reminder must be private and protected from outside eyes. Good wording for such a reminder is "This is to remind you to take a few minutes to complete and return the survey we recently sent you." In the follow-up, add or use language that will encourage a response, such as, "Your opinion is very valuable to us, and we want to include your input in our study." The wording of reminders should be general and neutral to encourage survey completion and return. Do not threaten or even appear to be negative. For example, do not say, "If you do not complete and return the survey, no one will care what you think or know about STDs."

A follow-up or reminder should have enough information for the recipient to identify the survey. Alternately, the survey (or link to the survey) can be re-sent with the survey reminder note. How many reminders to send and when to send them should be part of the decision making that is done in the initial methodology planning for the research project. Although there are no fixed rules for follow-ups, 10 to 14 days is usually reasonable. Subsequent reminders can be sent at four weeks. More than two reminders are probably a waste of time.

EXHIBIT 7.2 Example of a Reminder via Email or Mail

REMINDER

A few weeks ago, you received a "Learning Assessment Survey" from me. It was distributed through your program via email. If you have not completed the survey, please take a few minutes to do so and hit the submit button. If you need the survey site, please contact me. The information you provide through this survey will be helpful to me in my study of how students learn and, hopefully, to education in the future.

Thank you for your time.

Dennis Blessing, State University
Phone number
Email address

Follow-up reminders can be done in several ways. One way is to send a reminder to everyone who was sent a survey. The other way is more economical if surveys have identification codes. If the survey is coded, the investigator can identify who has returned a survey and send follow-up reminders only to those subjects who have not responded. An explanation must be done for any codes that appear on a survey or a reminder. Subjects should be informed of what the number is and how it is used. Remember, if some type of code is used, the respondents are not anonymous. It is very important that their information be kept confidential. **EXHIBIT 7.2** is an example of a reminder message used by the author.

Types of Surveys

Web-Based Surveys

Web-based surveys have become the most common delivery method used to gather data on healthcare professionals. Typically, the survey is distributed using an email that contains a Web address (URL) for the survey or through a third-party survey platform. Two key advantages to

Web-based surveys are: (1) the sample size can be large and dispersed, and (2) a large amount of data can be collected. Another advantage of Web-based surveys is that results can be downloaded to a database, eliminating data entry and its associated errors, time, and costs. Major limitations of Web-based surveys are the potential for a low response rate and respondent misinterpretation of items. In addition, the target sample must have a computer with online access. **TABLE 7.6** lists some of the positives and negatives of Web-based surveys.

An obvious advantage of Web-based surveys is that they can incorporate visually attractive photographs and illustrations in color that are difficult and costly to reproduce in print. A Web-based survey can be longer without increasing the costs of delivery. In fact, the cost of administering a Web-based survey is the hosting fee, which is not dependent on the amount of activity at the site. A number of commercial company's design surveys and help with data collection. Typically, these sites are user-friendly and economical if the investigator does not have the time, skill, or tools to develop their own surveys. Intuitively, it would seem that Web-based surveys are more cost-efficient, but an investigator must explore the costs when using a survey development site. Some sites are a one-time fee, some on-going fees, and some fees are based on the level of service.

TABLE 7.6 Aspects of Web-Based Surveys

Aspect	Comment
Cost	Low; usual cost is a fee required by the Web company
Personnel	Investigators only; requires no training of interviewers or field workers
Sample size	Can be very large; can be general or a specific population set; can be geographically wide or distant from investigator; requires an email address and subjects must have a computer
Response rates	Potentially low; a response rate greater than 30 percent is rare[1]
Data	Potential for quantity, but the quality is limited by respondent interpretation of survey items; only survey item data can be collected
Bias	Relies on respondent interpretation of survey items; non-respondent bias is high
Subjects	Not under pressure to respond; less intrusive than person-to-person contact

Internet surveys are associated with certain advantages:

- Data are immediately available when the respondent submits the survey.
- Results can be loaded directly into a database for analysis.
- High-quality graphics and detail can be used.
- Respondents can be "skipped" to appropriate items based on responses.
- Statistical analysis is facilitated because data are in a format for analysis.

Of course, one significant disadvantage of Internet surveys is that respondents must have a computer. The United States Census reports that 85.1% of US households have a computer with 79.9% with Internet access.[2] One limiting factor is that computer users tend to be adults younger than age 55. The rate for computer use by adults over 55 years drops to 59.2%.[2] Therefore, a consideration in using the Internet in survey research is the demographics of the study population. Sampling may also be a problem because access to Internet addresses or some form of notification is required to facilitate subjects to log on to an Internet survey. Email may be one way to contact subjects and provide an URL to a survey, or subjects may have to be contacted by direct mail. Whether or not response rates are higher with Internet surveys is open to question.

Telephone Surveys

Political parties and pollsters seem to love telephone surveys, particularly near election time. Interviewing by telephone can provide very timely information. **TABLE 7.7** presents some key aspects of telephone interviewing as a survey format.

One obvious limitation of telephone surveys is that subjects must have a telephone. Telephone interviews allow for some personal contact between the respondent and the interviewer while maintaining a moderate level of anonymity. This may be very valuable when dealing with sensitive or personal information. Speaking directly with a subject allows the interviewer (or investigator) to interpret survey items, to move through the survey based on responses, and to clarify responses. Cost may be a major factor in telephone surveys because interviewers often must be trained and paid. Telephone costs increase if long distance is needed or if many subjects must be contacted. The "annoyance factor" must be considered. Individuals may not want to be called or to have their routines interrupted by the phone ringing. The length of time a respondent is willing to be on the phone will influence their responses. The longer the subject is on the phone, the more likely they are to hang up.[1]

An investigator must also consider the type of responses that will be allowed in a telephone interview. Are subjects asked to respond to specific choices or are they allowed to respond in an unrestricted manner? Quantifying open-ended

TABLE 7.7 Aspects of Telephone Surveys

Aspect	Comment
Cost	Actual telephone costs, such as long distance. Training costs of interviewers. Interviewer time costs.
Personnel	May require multiple interviewers. Interviewers can telephone from one location. Skilled interviewers get better and more complete responses.
Sample size	Subjects must have a telephone. Size determined by investigator and funding. Can be large. Can be geographically dispersed.
Response rates	Vary, due to the willingness of subjects. The timing of call may influence the willingness of respondent to participate.
Data	The potential for moderate amount and quality of data based on number of subjects willing to participate.
Bias	Interviewer's manner, voice inflections, and interpretation of survey items may influence subject responses.
Time	Study can be conducted over a short period. Responses are immediately available.

responses may present some analysis difficulties. Response recording must also be considered, particularly with open-ended questions. Remember, if a telephone interview is recorded, the respondent must be informed and agree.

Personal Interview Surveys

Person-to-person, face-to-face interviewing has several advantages and disadvantages (**TABLE 7.8**). Interviews must occur where people are (e.g., office, mall, hospital room, home, clinic, school, etc.). Special sites can be utilized, but something must entice the subject/respondent to travel to a special site. If a special site is used for the survey, specifically scheduled appointments for the interview may work best. Person-to-person interviewing requires contact between the subject and the investigator or interviewer.

TABLE 7.8 Aspects of Personal Interview Surveys

Aspect	Comment
Cost	High; takes time and people
Personnel	Requires training
Sample size	Tends to be relatively small because of the time needed to conduct interviews
Response rates	Can be high once respondents agree to be interviewed; face-to-face encounters may improve or facilitate response and allow for clarification of responses
Data	Varied, time may limit the amount
Bias	Interviewer bias, interviewer influence on the subject
Time	Training and interviews take time

Unlike a telephone respondent, who can be influenced by the interviewer's voice, a personal interview respondent can be influenced by the physical being and bearing of the interviewer and the site of the interview. Also, the interviewer's voice inflections, facial and body movements, personality, and animation may influence responses. For these reasons, interviewer training must be more exact and extensive. Supervision of interviewers may be required. Risk of interviewer bias is high. The time needed to train interviewers and the required time for interviews are factors to consider in personal interviews.

Interviews can be used to collect qualitative and quantitative data. They can allow for greater exploration of subject responses and can add detail that may help interpret or understand responses. Certainly, if a product is being investigated, subjects can see and handle the product. The types of allowed responses must be considered in a personal interview process. How responses are handled is something that should be planned for as part of the methodology. A decision on how responses will be handled cannot be made after data collection.

▶ Survey Item Construction

Survey items must provide data that answer the research questions, hypotheses, or null hypotheses. Before any survey is constructed, much less applied, the purposes of the study must be defined. The best format for defining and guiding survey research is to use research question(s) or hypotheses as outlined in **TABLE 7.9**. This does not exclude the use of null hypotheses.

Without a well-developed and defined research question, hypothesis, or null hypothesis, a well-designed survey cannot be developed. As a survey item is constructed, the investigator must ask, "How does the information or data gathered by this item help me answer my research question, hypothesis, or null hypothesis?" If the survey item does not provide part of the answer to the research question, it is not needed.

TABLE 7.9 Definitions

Type	Definition	Example
Null hypothesis[3]	A negatively worded statement about the relationship among or between variables. It does not necessarily mean or refer to zero or no difference, but provides a hypothesis that is "rejected" or "accepted."	There is no difference in 5-year myocardial infarct rates between angina patients treated with a calcium channel blocker (CCB) and those treated with a beta-blocker.
Hypothesis[3]	A statement about the relationship among or between variables. This statement may be conjecture or prediction of a relationship or outcome.	Patients with angina who are treated with a CCB will have a lower number of myocardial infarctions after five years than patients treated with beta-blockers.
Research question	Similar to a hypothesis, but is constructed as a question.	Will angina patients treated with a CCB have fewer myocardial infarctions after 5 years than patients treated with a beta-blocker?

Demographic Data

Surveys almost always collect some demographic data. In many instances, the demographic data provide the basis for comparison groups. Demographics can be used to define and identify your study sample. Some common types of demographic data are age, gender, occupation, and education. For healthcare professionals, some types of demographic data are practice location, practice specialty, length of time in practice, number of patients seen, and procedures performed. Demographic data are the information that describes or characterizes the subject, sample, or population in some way. Demographics often strengthen the extrapolation of a sample result to a population by demonstrating how similar the sample is to the population. Most demographic data comprise nominal data. In the past, demographic information was usually collected at the beginning of the survey, but there is no reason it cannot be collected at the end. In an interview setting, it may be best to get to the heart of the survey first and save the routine demographics for the end.

Demographic survey items should be straightforward questions about the information sought. Here are some examples:

- What is your gender?
- How old are you?
- What degree did you receive from your program?
- What is your practice specialty?
- How long have you been in practice?

When constructing these survey items, a direct response is probably better than using a range as a choice. An example is age. You may want to group respondents by age, but it is better to have each respondent give their exact age and then group the responses if that method fits the project needs. **BOX 7.1** gives an example.

BOX 7.1 Example: Age Demographic Questions

What is your age in years? ________________

Versus

What is your age group in years?

A. 21–25
B. 26–30
C. 31–35
D. 36–40
E. > 40

BOX 7.2 Example: Salary Question

What is your annual salary? ________________

Versus

What is your annual salary?

A. < $25,000
B. $25,000–49,999
C. $50,000–74,999
D. > $75,000

When collecting sensitive or private information, however, it may be better to group responses. One example is the salary demographic. Respondents may be more willing to provide salary data in a range rather than their exact salary. This provides some degree of privacy. Data in ranges may also be useful when respondents cannot recall information precisely, as shown in the example in **BOX 7.2**.

The following are some points to remember when gathering demographic data:

- Be specific with the statements or questions. Specify the unit of measure. For example, if time-related information is sought, specify whether the time interval is in weeks, days, months, or years.
- When using ranges, make sure they do not overlap; this could lead to confusion. Using salary as an example, how can a respondent accurately answer the question shown in **BOX 7.3**, when the options overlap?
- Avoid asking for the same data in more than one statement or question.
- Use short, to-the-point, but understandable statements or questions.
- Ask only for information that is relevant to the study. The construct of a survey item should make it clear to the respondent why a piece of data is needed for the investigation. Do not be overly invasive unless the data are essential to the project.

BOX 7.3 Example: Unclear Salary Question

What is your annual salary?

A. $50,000 or less
B. $50,000–60,000
C. $60,000–70,000
D. $70,000–80,000
E. $80,000 or more

The Survey Instrument

The heart of the survey consists of items that provide the data for the investigation. The construct of these items influences respondent rates, willingness to answer, and quality of the data for analysis. Survey items that provide unequivocal data ensure reliability and validity. *Survey items must be short, clear, exact, understandable, and answerable.* Items must be designed to provide the data needed to answer the research questions, hypotheses, or null hypotheses. An investigator must decide on a format for the survey items and questions; however, it is not unusual for surveys to include a variety of item formats.

First Thing's First

Developing survey items is a process that goes from very general to very specific. One way to start is to sit down and write down every possible question even remotely related to the investigation. This brainstorming approach helps develop a list of considerations for the survey. This list does not have to be neat, orderly, grammatically correct, or even very specific; it is the beginning of the critical thinking for the development and building of the survey. A brainstorming list is often very expansive and far longer than the final product. Team members and colleagues can provide valuable assistance at this stage. Seek consultation on ideas and specific points, if needed. Good research surveys are rarely the result of one person's efforts.

Once general thoughts have been recorded, the investigator can begin to edit, define, delete, combine, categorize, and develop the specific survey items. Refining the survey and its items is often a long process and always aimed at improving the survey. Although there is always room for improvement, at some point development must stop and the survey finalized. One question that may help decide when a survey is ready is: Does each survey item provide some aspect of the answer to the research question?

Item Format

The format of survey items is dependent on the information sought. There are two basic forms of survey items: structured and unstructured (or open-ended).[1] Some examples of open-ended questions are listed in **BOX 7.4**.

These types of questions may remind health-care professionals (and students) of the essay questions that everyone hated (or hates) in school. Open-ended questions certainly have value, but they may be difficult to quantify or interpret. Structured survey items, in contrast, allow the investigator to control responses to a large degree as well as define the responses as values that are more statistically useful to the study. The formats of structured survey items vary; examples are presented in **TABLE 7.10**.

The choice of format depends on the data sought. When constructing the survey items and the possible responses to those survey items, it is important to state whether more than one option can be selected. This prevents misunderstanding by the respondents. **BOX 7.5** provides an example using activities related to earning continuing education units (CEUs).

BOX 7.4 Example: Open-Ended Questions

1. What do you think are the benchmarks for a quality medical practice?
2. What do you do to stay up-to-date with your practice?
3. What is the best way to deal with noncompliant patients?

TABLE 7.10 Examples of Survey Item Formats[1,4,5]

Item Format	Example
List responses	A checklist of responses or multiple choices.
Semantic differential scale	A scale defined by its extremes, with a range between the extremes.
Comparison scale	The choice between two or more items.
Visual analog scale	Indicates the intensity of subjective experience on a continuum.
Picture scale	Series of pictures/drawings indicate a response; may be useful for children or people who cannot read.
Forced ranking	All items in a list are ranked.
Ranking versus rating	With rank items, each ranking value is used once; rating values may be repeated for different items.

Ranking is a more robust method for obtaining meaningful results.

Specific wording can be used in the item stem, as shown in **BOX 7.6**. (The items in Box 7.5 also could be worded in this manner.)

In developing survey items, an investigator must try to eliminate subject interpretation errors as much as possible. Ultimately, no investigator can guess how respondents will interpret what is written or asked. It may be clear to the investigator but not to the subjects. A pilot test helps reduce interpretation errors.

BOX 7.5 Example: Wording Format

What activity do you prefer for earning continuing education credits?

(Check all that apply.)

A. _______ Formal lectures
B. _______ Hands-on exercises
C. _______ On-the-job experiences or consultations
D. _______ Patient/case studies
E. _______ Seminars/expert panels

Versus

What activity do you most prefer for earning continuing education credits?

(Check only one.)

A. _______ Formal lectures
B. _______ Hands-on exercises
C. _______ On-the-job experiences or consultations
D. _______ Patient/case studies
E. _______ Seminars/expert panels

BOX 7.6 Example: Alternate Wordings

Check all the activities you prefer for earning continuing education credits.

Versus

Check the one activity you most prefer for earning continuing education credits.

BOX 7.7 Example: Ranking

Rank each activity in the order of your preferences for earning continuing education credits.

(1 = most preferred, 5 = least preferred)

Rank all items.

A. _______ Formal lectures
B. _______ Hands-on exercises
C. _______ On-the-job experiences or consultations
D. _______ Patient/case studies
E. _______ Seminars/expert panels

Rankings

The ranking of responses is valuable in many cases. An example using the previous material may resemble the example presented in **BOX 7.7**.

In this case, the investigator ensures that the ranking numbers (1–5) are defined and specifies whether all items should be ranked. This example could state "Rank in order of preference those items you use to earn continuing education credits: 1 = most preferred, 5 = least preferred. Do not rank items you do not use." This may be a long statement, but it clarifies both what data are sought and what the respondent is to do. In some instances, it may be desirable to rate some items with the same value. Two examples of the rating approach are given in **BOX 7.8** and **BOX 7.9**.

BOX 7.8 Example: Rating

Rate the value to you of each of the following continuing education credit delivery formats.

(Rate all)

1 = Preferred, 2 = Acceptable, 3 = Not preferred

_______ A. Lecture
_______ B. Workshop
_______ C. Video
_______ D. Computer program
_______ E. Monographs

BOX 7.9 Example: Alternate Rate Format

Rate the value of each of the following continuing education credit delivery formats.

Rate all items 1–5, with 1 being the most valuable and 5 being the least valuable.

_______ Lecture
_______ Workshop
_______ Video
_______ Computer program
_______ Monographs

In some instances, a two-level question may be a better construct, where respondents indicate "preferred" items, then rank their preferred choices.

Ranking or rating systems should be defined clearly. Using the number 1 is a common format for the most preferred or highest value, but sometimes a reverse rating (e.g., 5 as the most preferred to 1 as the least preferred) may be useful or desired. The instructions to the respondents must be very clear. The item format must be completely consistent. If more than one item format is used, group similar format items together. This is space-efficient and will help in survey presentation and is less likely to confuse respondents.

The Likert and Verbal Frequency Scales

Verbal frequency scales are very common tools in survey research. One of the most common types of verbal frequency scales is the Likert Scale (pronounced Lickert). This is an ordinal scale used to gather information about respondents' opinions or positions on the subject under investigation. The true Likert Scale uses the values shown in **BOX 7.10**.

The descriptors can be reversed where descriptor 1 is *strongly disagree*, and 5 is *strongly agree*. Remember, the number does not matter because this is ordinal data, not continuous data; however, these types of scales are often treated as interval data in large samples with normal distributions. Analysis by parametric tests may be misleading. A statistician should be consulted about handling ordinal data as continuous data.

Investigators sometimes use a scale like this one, but with different descriptors or an increase in the number of descriptors. In these cases, the scale should be termed a "Likert-like scale" or, more accurately, a "verbal frequency scale."[1]

BOX 7.10 The Likert Scale

1. Strongly agree
2. Agree
3. Neutral
4. Disagree
5. Strongly disagree

BOX 7.11 Example: Verbal Frequency Scale

How often are ACE inhibitors given as the first drug in hypertension therapy?

A. Always
B. Often
C. Occasionally
D. Infrequently
E. Never

An example of a verbal frequency scale about angiotensin-converting enzyme (ACE) inhibitors used for the treatment of high blood pressure is given in **BOX 7.11**.

Regardless of the descriptors used, verbal frequency scales are very powerful and popular research tools.[1] **BOX 7.12** lists keys for using verbal frequency scales.

BOX 7.12 The Likert and Verbal Frequency Scales: Keys for Their Successful Use

Be clear in the instructions.
Use direct statements.
Avoid redundancy.
Address one element in each item.
Group survey items in sets of 5–10.
Make sure word responses are appropriate for the item statement or question.
Make sure scale responses are logical for the item statement or question.
Allow for neutral responses if possible.
Use terms that are easily understood.
Be consistent in formal as much as possible.
Avoid overlap of grouped responses, and make sure response options are logical for the question asked.
Have a survey pilot tested or reviewed by an expert.
Always proofread everything that is distributed to subjects.
Have someone else proofread the survey prior to distribution.
Make it short and simple; the shorter the survey, the more likely it will be completed.
Number pages: 1 of 4, 2 of 4, 3 of 4, etc.
Allow respondents to comment at the end of the survey.

BOX 7.13 Verbal Frequency Scale

For each of the following items concerning the ranking of programs, indicate your degree of agreement or disagreement using the Likert scale:

1. Strongly Agree 2. Agree 3. Neutral 4. Disagree 5. Strongly Disagree

	SA	A	N	D	SD
1. Physician assistant programs should be ranked.	1	2	3	4	5
2. Ranking programs will benefit society.	1	2	3	4	5
3. Ranking programs will help ensure the quality of PA education.	1	2	3	4	5
4. Only the top 25 ranked programs should be published.	1	2	3	4	5
5. The rankings of all programs should be published.	1	2	3	4	5
6. Program rank should be a component for accreditation.	1	2	3	4	5
7. Ranking creates ill will or loss of collegiality among programs.	1	2	3	4	5
8. Ranking creates unnecessary competition among programs.	1	2	3	4	5

Items in a verbal frequency scale ask the respondent to state his or her level of agreement with that item. However, a verbal frequency scale may indicate some responses other than agreement. Likert and other scales are used with a series of related survey items. Instructions for respondents should lead with a statement such as, “Indicate your level of agreement or disagreement with the following statements.” **BOX 7.13** is an example from the author’s research.[5]

Also, the instructions should ask respondents to respond to all survey items. Unanswered items lead to questions of validity, extrapolation, and analysis. Before the survey is administered, investigators should decide on how to handle nonresponses in the analysis.

When constructing survey items, ensure that the statement can be answered by the scale used. Avoid redundancy. Each item should address only one idea or concept. An example of a conflicting statement is shown in **BOX 7.14**.

The statement in Box 7.13 contains two separate components. A respondent may agree that ranking benefits society but disagree that ranking should be part of accreditation. Item clarity is key to accurate responses and sound interpretation of results.

BOX 7.14 Example: Conflicting Statement

Ranking health professions programs will benefit society and should be part of accreditation decisions.

When using verbal frequency scales, be sure that the choices reflect the responses that will provide the information needed for the investigation. Some examples of descriptors used in verbal frequency scales are given in **BOX 7.15**.

For some surveys, choices of “Not Applicable,” “Unsure,” “No Answer,” “Unknown,” and the like may be needed. In some instances, more or less than five responses may be needed. Regardless, there must be consistency in the options presented. Items and their responses must provide adequate choices on a continuum for the subjects’ responses. Consistency allows for appropriate analysis, which leads to more accurate conclusions.

Another key to developing survey items is that each item should have an equal number of positive and negative responses with a neutral response, if possible. This neutrality is not always necessary. For example, not offering the opportunity for neutral response forces the subject to make a choice. This approach is called a *forced response*. One risk

BOX 7.15 Descriptors for Verbal Frequency Scale

Very Satisfied	Satisfied	Neutral	Dissatisfied	Very Dissatisfied
Very Good	Good	Neutral	Poor	Very Poor
Highly Positive	Positive	Neutral	Negative	Highly Negative
Excellent	Good	Fair	Poor	Very Poor
Very Important	Important	Somewhat Important		Not Important

of the forced response approach is that respondents who are truly neutral may not answer. Therefore, decisions must be made as to whether the risk of a respondent not answering the question is acceptable or whether a neutral or non-committal response is acceptable to the investigation. Another option is to have a choice such as "does not apply" or "no experience" or "no knowledge."

Putting the Survey Together

Once the research question has been developed, the appropriate literature search completed, the methodology designed, and the survey items developed; the survey is constructed. Some introduction must be first. Few people will respond to a survey that begins with just the survey items. This is true for Web-based surveys, paper surveys, telephone surveys, and face-to-face interviews. For Web-based and paper surveys, a plain, easily read, black print on white background introduction is probably best. If a colored background is desired, light beige or gray may be acceptable. The survey should be organized, so that like items are grouped, particularly if some scale is used. Demographic questions, in the past, have been presented first, but recent trends have moved toward placing them at the end of the survey. It is the investigator's decision.

Assess the visual quality of the survey. Does it appear organized with well-defined borders, sections, and the like? Ensure the method of submission is clear. The submit button for an Internet survey must be very apparent and visible. A decision must be made about whether respondents already logged in to Web-based surveys can log out and return to the survey later. Proofread everything, and then have someone else proofread the survey. It is difficult to proofread one's work, particularly if the work has been repeatedly reviewed by its developer.

Pilot Testing the Survey

A pilot test is an excellent way to help ensure the survey is understandable, and the survey items gather the data desired, but a large group of subjects is not needed. Ask pilot test subjects to evaluate the survey, that is, give feedback on their feelings, interpretations, and suggestions for improvement. The pilot-test group or a separate group can participate in a focus group for review, feedback, and critical comment. Do not take critical review personally. The critical review is an important step toward making the survey as perfect as possible.

Some of the things to ask pilot study or focus group participants are:

- Are there too many survey items?
- Is the time needed to complete the survey too long?
- Are the survey items clear, concise, and easy to understand?
- Are item responses appropriate for the survey item?
- Are the directions for completion clear and understandable?
- Does the survey provide the data and information sought?

- Are there biased responses or leading items?
- Is the survey format visually acceptable or pleasing?
- Are there suggestions for improvement?

Remember that even before a pilot study, appropriate institutional approval is required. Institutional review board (IRB) or research ethics committee approval must be obtained in writing and maintained in study files. Do not survey participants until IRB approval is granted in writing. To do so, even if approval is forthcoming, would be unethical. Once all these small steps are completed, start the study.

When results begin to accumulate, work on the investigation regularly. The most efficacious way to proceed is to set aside a specific period each day for working on the project. Keep good records, protect confidentiality, do the follow-ups, and set a deadline after which no further data will be accepted. Data cannot continually be added indefinitely. At some point, data analyses must start. Once analyses are completed, the conclusions can be drawn. *Remember:* If the methodology is sound, the analyses are appropriate, confounding variables are controlled, and study biases are minimized, the results are the results. As a researcher, the search is for "truth," not "hoped for" outcomes. Ultimately, the most that the majority of research efforts contribute is just one very small piece of information in the universe of knowledge.

How Many Subjects?

How many people (subjects) should be surveyed? If the population of interest is small, survey the entire population. One good example of a fairly easy population to sample is a specific healthcare profession's educational programs. Another example might be all of the occupational therapists who work only in nursing homes in communities with a population of less than 5000. In these cases, the sample and the population are the same. In some instances, a convenience sample may be obtained. As the name implies, the sample subjects are convenient for the investigator to survey. One example is faculty members who survey students in their programs or classes. These subjects are convenient; however, a convenience sample may *not* be representative of a population. In this example, students in a healthcare profession program may be demographically different from students in another or similar program. A convenience sample presents problems with extrapolation to the larger population. Convenience samples are of very limited benefit.

An investigator wants the sample to represent the population to be studied. However, consideration of costs and logistics in setting the sample size must be part of the methodology. In other words, an investigator must be able to afford the costs of the study and to handle the survey distribution and analysis. Remember, a larger number of respondents does not necessarily increase the accuracy of the results; a good response rate from a smaller sample may be better; however, the sample must represent the population. Small sample groups are more likely to be different from the population than large or multiple sample groups.[1] The survey instrument must be valid and reliable.

Confidence Level and Interval

Every investigator must accept the fact that there is always a chance of error. There are some ways to try to control some inherent errors. First, set a confidence level and a confidence interval. (See **BOX 7.16**.)

BOX 7.16 Confidence Level and Interval

Confidence level: The desired percentage of scores that falls within a certain range of confidence limits. It is calculated by subtracting the alpha level from 1 and multiplying the result by 100.[6]

Confidence interval: A range of values of a sample statistic that is likely to contain a population parameter. The wider the interval, the higher the confidence level.[6]

The confidence level is usually set at 95% or 99%. This means that one can state with 95% or 99% confidence that the results are within the margin of error. The confidence interval is the margin of error, usually expressed as a range (e.g., 3–5). The size of the population must be known. With these pieces of information, the sample size can be calculated. Many statistical texts and websites have tools for determining sample size. Some statistical computer programs will do the job. If there is difficulty in determining sample size, consult a statistician.

What Statistics to Use?

Again, it may be wise to consult a statistician to determine the best statistical tests to use for analysis of the results. Statistical tests can be bewildering, and most of us need help from an expert. However, make the analysis decisions part of the initial planning for the methodology, not after the data are collected. Consult a statistician early in the planning. Demographic data can be presented as percentages and, if necessary, can be compared to known population data. This is a good way to demonstrate the sample is like the population of interest. Another key to successful survey strategies is to understand what the statistical tests mean and what they demonstrate. Use statistical tests that fit the data and meet the study needs.

Summary

Surveys can provide a wealth of useful information. Survey research requires the same attention to detail as any other part of any research project. The same process is used in survey research as with any other type of research. Survey and survey item construction are the keys to success.

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CHAPTER 8

Qualitative Research

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CHAPTER OVERVIEW

The complexity of the healthcare environment often demands a different methodology than the quantitative approach. The purpose of this chapter is to provide an introduction and overview of qualitative research as it relates to health care. The terminology in qualitative research differs from that of quantitative research, so a comparison of terms is provided. This chapter also discusses how to design and implement an essential qualitative investigation in health care and some other related fields, as well as some appropriate ways to assess the quality of a qualitative study and some basic differences in qualitative research approaches.

LEARNING OBJECTIVES

- Define qualitative research.
- Discuss the differences between qualitative research and quantitative research.
- Describe when a qualitative design is the preferred methodology for a project.
- List and discuss the techniques used in qualitative research.
- Design a research project combining qualitative and quantitative methods.
- List and description of qualitative research approaches.

Introduction

Qualitative research answers different kinds of questions than quantitative research does. Quantitative studies answer questions that begin with the words "how much" or "how many."[1] In contrast, qualitative studies answer questions that begin with the words "what," "how," or "why." The two approaches are often complementary in healthcare studies or as a part of a continuum in a research study. When both types of investigation are employed concurrently, the study is termed a *mixed-methodological* study.[2]

Historically, many healthcare researchers have criticized and avoided qualitative methods. Those investigators believed that all research should be objective and that subjectivity should be eliminated to ensure reliable findings.[3] However, healthcare researchers are becoming more familiar with qualitative methodologies; their potential to enhance understanding of the phenomenon that patients, physicians, nurses, and others face; and the expansion of the knowledge obtained quantitatively.[3]

In many cases, healthcare professionals are interested in objective proof that a treatment works. Quantitative studies are the preferred way to measure such outcomes. However, healthcare professionals treat human beings, unique individuals who are suffering and feeling in different ways. Qualitative studies shift the investigation away from the lab and into settings where the care is rendered. Truth is revealed in human experiences rather than in blood tests or imaging. Interviews and observations are used to collect data. The patient interview and observation are familiar ways to gather data about medical conditions; however, interviews and observations can reveal much more than the patient's health history. Healthcare professionals may choose a qualitative research approach to study such topics as:

- The human experiences of illness
- The human experiences of care
- Interactions among clinicians, patients, and families
- Lifestyle interventions
- Quality of life
- Cross-cultural perspectives
- The caregivers' experience
- Experiences after treatments and/or health training.

Qualitative investigations can produce meaningful results that humanize and alter healthcare practice. The purpose of this chapter is to provide an introduction to essential qualitative research as it relates to health care and some other related fields.

Many terms fall under the umbrella of *qualitative research* including approaches such as case studies, naturalistic inquiry, phenomenology, ethnography, grounded theory, life history, content analysis, and narrative analysis.[1,4] The authors acknowledge this chapter is introductory and risks oversimplifying complex topics related to various qualitative methodologies. However, it is possible to introduce many of the key aspects of qualitative research by discussing an essential qualitative study.[1] After completing this chapter, the reader should recognize the applied qualitative process in healthcare research and be able to discuss how to understand and critically evaluate a qualitative study and its different elements and process. Those individuals interested in becoming qualitative researchers will need to seek additional training and resources beyond this introductory piece. At the end of this chapter, a list of references and additional readings are provided for that purpose.

Philosophical Perspective

In contrast to the rationalistic or positivist paradigm of quantitative research, qualitative research falls within interpretivism, also called constructivist paradigm. The paradigm operates on the assumptions of subjective reality and multiple truths, rather than an objective reality and a single truth.[5] Furthermore, the paradigm values the lived experiences of individuals.[5] For this reason, interpretive study designs are sometimes more suitable than rationalistic and traditional designs to understand the human being and his/her experiences. Although many approaches to qualitative research exist, naturalistic approaches focusing on the clinical environment are well suited for healthcare research. The primary purpose of such studies is to understand and interpret reality as defined by individuals through their experiences in natural settings.[1]

Comparing Quantitative and Qualitative Research in the Healthcare Field

Qualitative research can feel foreign to individuals accustomed to the traditional quantitative perspective, particularly in the healthcare field. Although the two approaches are often complementary, it is important to understand some key differences between qualitative and quantitative studies in this field. To some extent, the researcher's role, reasoning, sampling, data collection, analysis, reporting, and study validation measures differ between quantitative and qualitative studies. **TABLE 8.1** outlines some of the key characteristics of these two methodologies in the healthcare field. Furthermore, the terminology used by qualitative researchers often differs from the terminology used by quantitative researchers. **TABLE 8.2** includes a comparison between terms regarding rigor and validity in both traditions.

Researcher's Role

One of the key beliefs of positivism is that the researcher is objective and distant. Interpretivism, however, does not require adherence to the belief in objectivity.[5] The qualitative researcher gains access to the participants' natural environment and is the main research instrument used to collect data. Subjectivity is seen as valuable and inevitable; however, the qualitative researcher also understands that bias may influence study outcomes. Acknowledging that it is difficult to eliminate bias, qualitative researchers present their biases "up front" in a positionality statement that is included in the study results section.[1] This positionality statement allows subjectivity to be revealed and gives the reader the opportunity to consider the researcher's stance in relation to the research findings.[5] The positionality statement

TABLE 8.1 Key Differences Between Quantitative and Qualitative Studies in Health Care[5]

Element	Quantitative	Qualitative
Researcher's involvement	Detached	Participatory
Researcher's stance	Objectivity	Subjective confirmability
Setting	Controlled	Naturalistic
Sampling	Random population-based	Case-based/purposeful
Methodology	Positivist method	Naturalistic inquiry
Data	Numbers	Words
Analysis and reasoning	Hypothesis testing Deductive	Hypothesis generation/working hypothesis Inductive
Reporting	Statistics	Themes/categories
Study validation	Internal and external validity	Trustworthiness

TABLE 8.2 A Comparison of Quantitative and Qualitative Studies Terminology Regarding Validation and Rigor[5]

Traditional Terminology	Qualitative Terminology	Purpose
External validity (generalizability)	Transferability	Establishes a relationship between the study's results and the world outside of the study
Internal validity	Credibility	Ensures the study's processes are performed in an appropriate and rigorous manner
Reliability	Dependability	Signifies the level of confidence in the study's data collection methods
Objective reproducibility	Confirmability	Assesses the ability of researchers to accomplish a similar study and replicate the results

typically includes the researcher's assumptions, values, and reasons for choosing the research topic. The researcher reflects on potential biases and makes them transparent to the reader. Quantitative investigations rarely contain such explicit descriptions of the researcher's views. In contrast to the quantitative researcher who relies on the assumption of objectivity, the qualitative researcher relies on confirmability and transferability,[6] a topic discussed later in this chapter.

Settings

Many quantitative investigations occur in laboratory settings where potentially extraneous influences on the study's outcome can be controlled. Traditional researchers working outside of the lab also attempt to control the participants' environment. In contrast, qualitative investigations often take place in natural social settings without imposing controls. Healthcare settings are a source of rich qualitative data. An investigation may occur in a single setting or multiple settings. For example, an investigator may interview several patients in a single dialysis center or conduct focus group interviews in multiple centers. Researchers can observe different treatment settings and explore how patients experience health care in those settings.

Sampling

In quantitative studies, researchers seek to provide answers for a population by using a statistical representative random sample, a process called generalization.[7] Although these researchers obtain their samples in different ways, the most common approach is through random population sampling. Random sampling is performed to minimize the chance of forming a participant group that differs from the population from which the sample is drawn.

In contrast, most qualitative researchers employ nonrandom purposeful sampling to select sources of rich data. Qualitative researchers may study the story of a single individual or the experiences of a large group of individuals. When sampling, qualitative researchers consider the comparisons and distinctions needed to answer their research questions.[8] The individuals sampled may have shared and differing characteristics with each other. Therefore, the researcher may wish to limit the study to a homogenous group, or may purposefully sample individuals who are heterogeneous to provide for maximum variation and representation.[9] In contrast to quantitative researchers, who often determine the size of their samples based on statistical measures, qualitative investigators initially estimate how many participants are needed to reach thematic saturation.[5] Thematic saturation occurs when the information obtained is redundant and no new information is forthcoming.[10]

Methodology

Traditional/positivist research designs include pre-experimental, experimental, and quasi-experimental designs. Quantitative investigations test for group differences, variable relationships, and causal explanations. In contrast, qualitative methodologies are primarily exploratory and descriptive.[5] Many of these methodologies are designed to find meaning and evaluate social settings.[4] Some of the more common qualitative research approaches include naturalistic inquiry, grounded theory, ethnography, phenomenology, and action-oriented research.[2] **TABLE 8.3** contains a list of the more commonly known qualitative research approaches with brief descriptions. Most importantly, qualitative investigators use the methodology that fits the research purpose and research questions.

TABLE 8.3 Qualitative Research Approaches

QR Approaches	Description
Naturalistic Inquiry studies	Focus on the realities associated with real contexts.[6]
Grounded Theory	Generates theoretical explanations for social phenomena.[2]
Ethnography	Explores the activities and relations within cultural groups.[2]
Phenomenology	Looks to understand a particular phenomenon in a particular context of a group, community, or society.[2]
Action research	Seeks solutions to local practical problems.[2]
Case study	Provides an in-depth exploration of a bounded system (e.g., an activity, an event, a place, a process, an individual, or an organization) based on extensive data collection.[2]

Data Types

Quantitative researchers measure things. The different types (scales) of quantitative data include nominal, ordinal, interval, and ratio. In contrast, qualitative researchers collect data from a variety of sources using different methods such as interviewing, observation, and document analysis.[6] Words, images, non-verbal communication, documents, and artifacts; not numbers, are the data.

Analysis and Reasoning

Traditional research involves hypothesis testing. The researcher forms a hypothesis prior to collecting data; this timing is called *a priori* or before the fact. In contrast, as qualitative studies evolve, working hypotheses are generated and are not based on a priori hypothesis testing. Qualitative researchers use inductive, not deductive, reasoning. In traditional investigations, the analyses are based on descriptive and inferential statistics; however, the qualitative approach to analysis is interpretive. The ultimate purpose of qualitative data analysis is to answer the research questions through methods such as content analysis, narrative analysis, and discursive analysis, among others.[1]

Reporting

Traditional results are reported using various numeric values such as the mean, standard deviation, and *p*-value. Quantitative results are often presented in tables and graphs. In contrast, qualitative results are presented as themes, not statistical results. The final thematic structure emerges through induction and is supported by units of meaning.[1] Many qualitative reports are organized by the research questions and are supported by direct quotes from the study's participants, which constitute the data or units of meaning.

Applying Qualitative Research in Health Care

Now that the differences between quantitative and qualitative research have been presented, the remainder of the chapter will review the essential steps of qualitative research. One approach to qualitative research that healthcare researchers use is the case study. The case study design is well suited to reporting qualitative research findings and generating working hypotheses.[5] Case studies in health care may resonate with the reader in a way that is concrete, contextual, and participatory.[1] Case studies are defined by the unit of analysis and any bounding conditions or criteria.[11] The unit of analysis can be an event, a person, a group, a program, an institution, or a process.[11] Bounding conditions can be geographic, temporal, or concrete.[11] For example, a case could be defined by a group of patients who are bounded by shared medical diagnosis and specific treatment location.

FIGURE 8.1 illustrates the flow of a basic qualitative study. The research purpose allows the investigator to define the research questions. The research questions then drive the methodology and methods of the study. In Figure 8.1, a purposeful sample is obtained, and different data collection methods are used. Data collected during the study are then systematically managed and analyzed. This process includes breaking the large volume of data into small units of meaning and then reassembling the units into emergent categories and themes.

The figure includes the option to use a computer or index cards to carry out this process. These options are a matter of personal choice; many times choices depend on the volume of data. In each case, the ultimate goal is to generate a report that contains rich data organized thematically to capture the essence of the case studied. The report should address the research questions and contain excerpts of data that support the researchers' results, conclusions, and recommendations.

Suggested Steps for an Essential Qualitative Study

1. Identify the research problem.
2. Define the purpose of the study and design the research questions.
3. Ensure the study design is consistent with the research purpose and research questions.
4. Complete a literature review on the topic and identify the theoretical framework.
5. Refine the research purpose and questions.
6. Reflect on potential personal biases, values, and assumptions.
7. Consider how participant sampling will occur.
8. Give a rationale for participant selection and define the criteria.
9. Obtain institutional review board (IRB) approval for the study.
10. Gain access to participants.
11. Choose data collection methods (observation, interviews, and/or document analysis).
12. Obtain informed consent from the study participants.
13. Collect a comprehensive data set (transcripts, field notes, and documents).
14. Assess the adequacy and depth of the data collected considering the research questions.
15. Divide data into smallest units of meaning (unitize).
16. Analyze data and assemble information into categories and themes using constant comparative analysis, content analysis, and inductive reasoning.

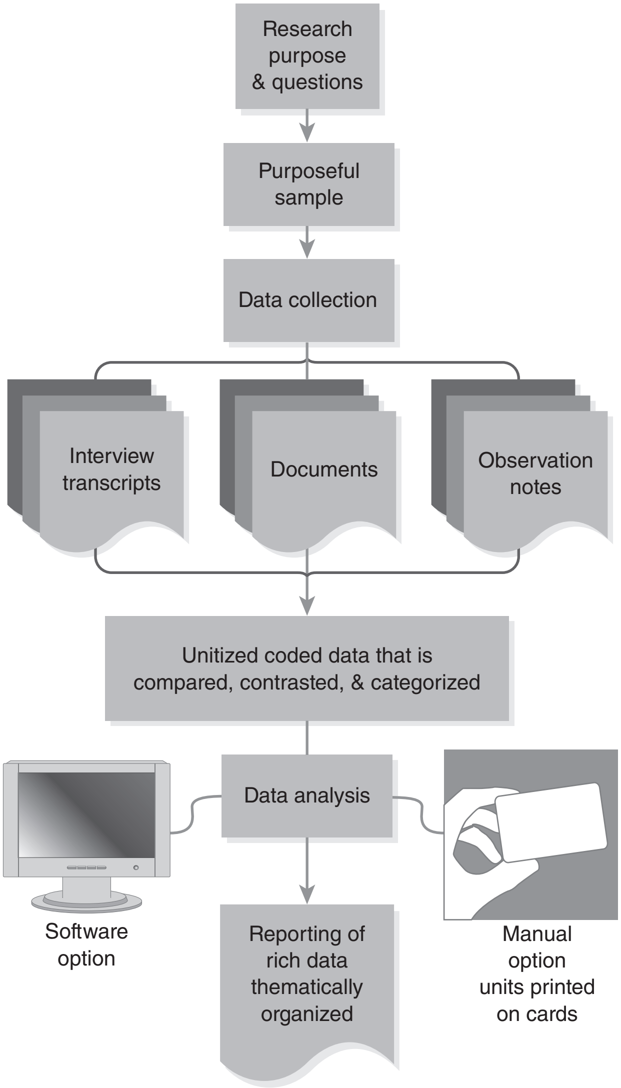

Research purpose & questions
Purposeful sample
Data collection
Interview transcripts
Documents
Observation notes
Unitized coded data that is compared, contrasted, & categorized
Data analysis
Software option
Manual option units printed on cards
Reporting of rich data thematically organized

FIGURE 8.1 Flow of an essential qualitative study.

17. Evaluate the theoretical framework/value of the results (novel theory, supports known theory, refutes known theory).
18. Define the clinical utility of the study in relation to similar patients or contexts and research questions.
19. Conduct the study in a systematic, auditable manner.
20. Report results, conclusions, and recommendations.

Qualitative Design and Implementation

The design plan must be flexible and adapt to field conditions; the design in qualitative research is called "emergent design."[6] Despite this flexibility, some pre-planning is required. The initial plan includes gaining access, participant sampling, data collection, data management, data analysis, and trustworthiness techniques to be used.[6,8,12]

Access

Investigators need to consider how they will access study sites by negotiating effectively with institutional gatekeepers.[5] Some researchers may ask questions that are sensitive and intrusive. Gatekeepers may refuse access when the investigation covers delicate issues. Even when access is allowed, researchers cannot assume that it will continue. Access should be considered an ongoing process that requires continued negotiation.

Participant Selection

Qualitative researchers use a multitude of sampling strategies, most of which are nonrandom and purposeful. **TABLE 8.4** contains a list of the more commonly used nonrandom sampling approaches with brief descriptions.

Data Collection

In qualitative inquiry, the investigator attempts to collect rich data not readily captured by other types of research instruments. To gather such data, researchers should use a variety of sources, different methods, and multiple senses.[6] Interviewing is the most common data collection method used by qualitative researchers, but it can be successfully combined with observation and document analysis.[6] Health professionals frequently use interviewing to gather information when taking a patient history. This process is systematic, sensitive and well-suited for research in the healthcare field. During the interview, researchers should listen carefully and avoid peppering the subject with questions. The interview is a conversation with a purpose that remains faithful to the research questions.[6] Investigators should avoid interruptions, leading

TABLE 8.4 Purposeful Sampling Strategies for Qualitative Research

Sampling Strategy	Description
Maximum variation	A wide range of individuals is selected to capture multiple perspectives.
Homogenous	Similar individuals are selected based on specific shared characteristics and criteria of the study.
Critical case	Individuals are selected based on their perceived value in addressing the research problem.
Theory-based	Participants are selected for their ability to support the generation of theory.
Snowball	Individuals participating in the study help the researcher find and recruit additional participants.
Extreme case	Participant(s) are selected due to an outlying characteristic that makes them different from others.
Typical case	Participant(s) are selected because they are representative of what is usual.
Stratified purposeful	A group of individuals is divided into subgroups to allow for comparison.
Convenience	The sample is selected based on accessibility.

Data from Onwuegbuzie AJ, Leech NL. A call for qualitative power analysis. *Qual Quant*. 2007;41:105–121.

questions, and conversational deviation. Data can be captured using audiotapes, digital recordings, handwritten notes, or a combination. Interview transcripts can be transcribed verbatim or with verbal fillers and extraneous pauses removed. Verbatim transcripts, however, allow researchers to assess the potential meaning of long pauses and verbal fillers. In addition, field notes can be incorporated into the transcript or left as a separate data source.

Data can also be obtained by observation. Qualitative researchers can collect observations as a participant or as a nonparticipant. Participant observation allows the researcher to experience the conditions of an insider. Such in-depth observation may yield insights unobtainable by other methods; however, the researcher risks "going native" and losing focus in the research problem unless they keep a critical distance.[4] Nonparticipant observation is direct but more detached than participant observation. The amount of information collected in both types of observation can be vast; therefore, qualitative researchers usually devise a plan or protocol to direct and focus the observations.[2]

Documents and artifacts are sources of data available to healthcare researchers. Documents are not just written items but can include photographs, videotapes, or DVDs.[6] Artifacts are other physical items that convey information about the participants or setting.[11] For example, the artwork generated by pediatric oncology patients would be considered artifacts in qualitative research.

Data Management and Data Analysis

A large volume of data can be collected in a naturalistic study. The volume may be a challenge to manage. A codebook, or coding database, helps the researcher keep track of the voluminous data. Qualitative research software, such as NVivo, ATLAS.ti, and Dedoose, can help researchers manage and access the data. Still, some researchers prefer to manage the data on index cards that can be color-coded and sorted manually when the volume of data allows it. Although the data management choice is a matter of preference, staying organized is the key to maintaining data integrity. Once the data are collected, they must be put into a useful form for the purpose of analysis. The data must be unitized. A single unit of meaning is the smallest meaningful piece of content that can stand alone.[5] Every single unit of meaning must be coded. Coding is a way of tagging the units to associate them with the source and begin the categorization process. In the following example, a patient is interviewed, and a transcript is generated. The coding process will be illustrated.

> Interviewer: *I am interested in learning about people's experiences when they are hospitalized. You recently had a serious injury that caused you to be a patient in the hospital. Would you talk to me a little about what it felt like to be a patient?*
>
> Jane: *I think that the biggest thing is that not many people have a sensitivity to a person who has back problems because that's what I had—a herniated disc—and I really don't think for days that they realized how much pain that was associated with injury. Um, they were making kind of light of the situation, asking me to move in positions of just getting out of normal clothes into a hospital robe and that didn't seem like a major task to them but, uh from my side it was excruciating to where I wanted them to cut the clothes off, but they insisted on literally moving my body around to get the clothes off to get the robe on, which gave me the sense that they had no earthly idea of what kind of pain I was in.*
>
> Interviewer: *So it sounds to me like you were really concerned that the staff did not understand the pain that you were in, how did that make you feel?*
>
> Jane: *Starting from the emergency room, I think that they would not even sometimes give me time to complete a sentence, that they would ask me something and before I—they would kind of judge how much I could tell them, um and they would always either cut me off or say oh that's fine, that's all we need to know for now. And they*

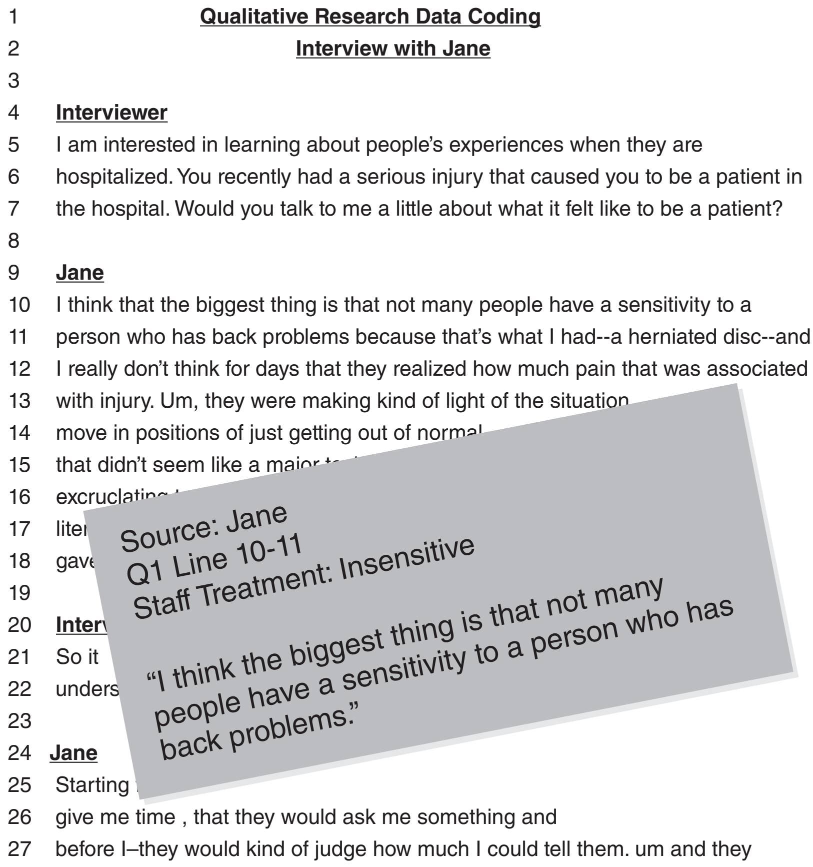
would never keep me posted like I was in the emergency room for hours and if you'd ask them if my doctor had been called or whatever—well we will get back with you in a minute—and it'd be another hour or two. Um, so you were laying there not necessarily being kept updated on your condition or what work they were doing and the a that just left you in a state of fear because you did not know what was going on and maybe they were doing the right things. But if they had just come in and said "you know we've called your physician and he's on his way" or "we haven't got a call to him in yet" or "we are tracking him down" or something, it would have allowed me to know that, it would have eased my mind knowing that they were doing their job and because the way it looked it was like I was just in another world—that they were doing their thing and I just happened to be the thing that they were kinda focusing on but not really paying much attention to. They were doing their thing kind of like outside of my issue. And it even happened in the hospital room. And even the nurses and whatever. You really had to hand-tie nurses and literally put them on the spot sometimes and make them stop and listen to you and answer your questions completely or hear you out because they were constantly cutting you off or saying "well it's in your chart." Well, this pill I've never taken before why am I taking it. "Well, because" <nurses>. And I just think a patient needs to know a little bit more than that and deserves to know more than that than being cut off and not being listened to.

Interviewer: *So it sounds to me like one of the biggest concerns that you experienced was that the communication you received was not helpful to you as a patient. Maybe we could explore that a little bit more and talk about what would have helped you more. You gave me a few examples, but what other kinds of things would have helped you as a patient to have understood what was happening to you?*

Jane: *I think when they were, I think that just extra time not feeling like you were being rushed to the point that where I think if they had just come in and done a little TLC or whatever and saying you must be in pain here, we are trying to do everything that we need to do. Tell me what happened, tell me where it hurts. Um, to the point of listening to my pain, not just seeing it. But listening to the pain; I think that would have helped me as a patient knowing that I was being cared for and that I just wasn't part of the shift; and that I was somebody that did need help. And I really felt that a lot of times, especially in the emergency room, that I was just a part of their paycheck. And that if the shift had changed, I don't know if I'd have known the difference. I don't think that one nurse—a new face would have come in and just taken right over and that made me feel like I was part of the shift; that I was not a person in pain that I was just a body that was in pain. And I don't think they had any perception of how scared people are in that situation and maybe need a little coddling and maybe need just a few minutes of their time to settle the anxiety down. You know before all the other stuff starts happening.*

Qualitative researchers often prefer that transcripts include the printed line numbers as shown in **FIGURE 8.2**. This procedure allows for data tracking. In addition, the researcher may prefer transcripts with wide margins to allow for annotations.

With these annotations, researchers document their first impression about the meaning of each unit. At some point, each of the units will be separated from the larger source document, either by computer software or manually on index cards. Figure 8.2 shows how a unit of data is transferred and coded by source and category.



1 **Qualitative Research Data Coding**
2 **Interview with Jane**
3
4 **Interviewer**
5 I am interested in learning about people's experiences when they are
6 hospitalized. You recently had a serious injury that caused you to be a patient in
7 the hospital. Would you talk to me a little about what it felt like to be a patient?
8
9 **Jane**
10 I think that the biggest thing is that not many people have a sensitivity to a
11 person who has back problems because that's what I had--a herniated disc--and
12 I really don't think for days that they realized how much pain that was associated
13 with injury. Um, they were making kind of light of the situation
14 move in positions of just getting out of normal
15 that didn't seem like a maior
16 excruclating
17 liter
18 gave
19
20 **Interv**
21 So it
22 unders
23
24 **Jane**
25 Starting
26 give me time , that they would ask me something and
27 before I–they would kind of judge how much I could tell them. um and they

Source: Jane
Q1 Line 10-11
Staff Treatment: Insensitive

"I think the biggest thing is that not many people have a sensitivity to a person who has back problems."

FIGURE 8.2 Unitization and coding example.

Although the figure shows only a single coded unit, readers are encouraged to read the entire excerpt and practice unitization and coding.

As a reminder, the ultimate purpose of data analysis is to answer the research questions.[1] The process is comparative, iterative, and inductive.[1] A frequent approach to qualitative data analysis is content analysis. In content analysis, the unitized and coded data from transcripts, field notes, and other artifacts are categorized to form a thematic structure.[13] Data are analyzed using constant-comparative analysis, so categories and themes are defined.[5] The themes are combined or subdivided as necessary until the final structure is revealed. Ideally, this process should begin even during the data collection phase.[1] Tentative themes will likely change as the process evolves. Induction occurs when these individual pieces of meaning are joined together to represent general concepts, or themes. The final themes and categories will support the responses to the research questions.

▶ Assessing the Quality of a Qualitative Study: Ensuring Trustworthiness

Although the reader determines if a qualitative study is trustworthy, specific criteria have been established. Trustworthiness covers all areas that ultimately determine the study's integrity: its truth value, plausibility, rigorousness of design and method, and the credibility of both data and researcher.[5] The four trustworthiness criteria used in qualitative research are credibility, transferability, dependability, and confirmability.[5] Each of these criteria has a set of corresponding techniques.

Credibility

Analogous to internal validity, credibility can be achieved through prolonged engagement, persistent observation, and triangulation.[5] Additional techniques that help establish credibility include peer debriefing, negative case analysis, referential adequacy, member checking, and reflexive journaling.[6] These techniques demonstrate the researcher's commitment to scholarly standards and the rigorousness of the study.

Prolonged Engagement

Investigators must first establish credibility with the participants. Prolonged engagement allows researchers to learn about the social setting while establishing a trusting relationship with the participants.[6] Prolonged engagement facilitates candid and truthful responses during interviews. Furthermore, researchers can learn details about the organization not discoverable in a single visit. Immersion allows researchers to experience the participants' reality.[12] During prolonged engagement, however, investigators should avoid psychological fusion with the participants or the organization. This fusion is called "going native," and it might compromise the research perspective.[5,6]

Persistent Observation

Early research findings can be superficial and incomplete. Persistent observation can be defined as a process of going deeper. Participants may give politically correct or deceptive responses.[6] Investigators must be alert for long pauses, verbal fillers, and body language that may indicate more information is lurking under the surface. The researcher is the measurement instrument and must be able to discern what is atypical versus what is irrelevant.[5]

Triangulation

Even a single experience or opinion can be meaningful. Credibility is enhanced, however, when the single experience can be verified. Triangulation can be employed when selecting sources, methods, and theories.[5] Triangulation enhances credibility by supporting or refuting research findings in a way not achieved by a single source, method, or theory. Researchers can triangulate sources by purposefully selecting individuals likely to experience a given phenomenon from a different perspective. The triangulation of methods is exemplified by a research design that uses a variety of ways to collect data. Triangulation of theories is achieved when the data collected are checked against multiple theories.

Peer Debriefing

In peer debriefing, researchers consult a knowledgeable peer for advice and ideas.[4] By using this external check; researchers are demonstrating that they consider other perspectives and lenses to see data and the study. Peer debriefing allows researchers to deal with emotions, test working hypotheses, and take a momentary outside stance during the study.[6] Ethical dilemmas can be discussed and resolved. This technique keeps the study on course.

Negative Case Analysis

Some researchers begin with fixed ideas about the anticipated results of their study. Negative case analysis is used in analytical induction and theory building. Using this technique, researchers "purposefully seek cases that apparently do not fit the explanation as formulated."[1] This iterative process allows researchers to reformulate their hypotheses by accounting for aberrant data.[5] Credibility is enhanced when researchers look for additional explanations for findings that do not initially fit.

Referential Adequacy

A control group is often used in traditional studies for the purpose of comparison. In a qualitative study, referential adequacy refers to the use of a separate set of materials collected in the study environment to reinforce the research findings.[6] For example, a subset of the data collected can be archived for later comparison.[5] Video recordings, photos, and other materials can be collected for the same purpose.[6]

Member Checking

Distortions often occur in human communication. Member checking is a frequently used technique that helps to minimize such distortions. Member checking is also the most direct means of testing research interpretations.[5] The most basic form of member checking occurs when investigators ask for clarification during the interview. Investigators can also summarize their understanding at the end of the interview and ask if the data collected accurately reflect the participant's statements. Participants can also check the transcripts and the researcher's interpretations after data collection happens.

Reflexive Journal

The reflexive journal serves a dual purpose: (1) it is a diary that documents the evolving nature of the researchers' relationship to the study, and (2) it is a place to keep track of logistical information.[6] The qualitative research process involves making meaning that is enhanced when researchers track their thoughts and experiences in a reflexive journal.[13] Reflexivity involves critical self-reflection.[4] The journal entries document the internal dialogue of the researcher during the course of the study. In addition, the journal allows the researcher to examine biases, assumptions, and tentative hypotheses continually. Reflexive journaling is valuable and enhances the study's credibility.

Transferability

The concept of transferability is similar to external validity. Qualitative investigators do not make statements that generalize the results to others outside of the study. Although external generalizability is not a qualitative research goal, thick descriptions may direct readers to draw conclusions about the relevance of the collected data in relation to similar contexts, which allows for transferability and replicability.

Thick description is not simply a detailed description, but one that has interpretive value.[4] The study's results can provide concrete examples that others use as a platform for additional inquiry, and understanding.[1] Thick description also includes a detailed explanation of how the study was conducted. The description should allow other investigators to replicate the study in a different setting. The following questions should be considered:

- How well does the author describe the lived experiences of the participants?
- How well does the author describe the participants and who they are?
- Does the author provide enough detail about the social, cultural, and physical context of the study?

Thick description answers these questions of relevancy without making claims about the application of findings outside the study's context. Human stories evoke human responses across contexts, thus making the research and sometimes the results transferable.

Dependability and Confirmability

Dependability, analogous to reliability, can be established by (1) using different methods, (2) splitting the data, and (3) conducting dependability audits.[5] A study that demonstrates internal consistency is dependable. Confirmability is similar to objective reproducibility and demonstrates an attempt to make the investigators' steps traceable. Dependability and confirmability rely on auditing procedures.

Audit Trail

Similar to a tax audit, the auditing process allows for an external review of documentation and decision making after the study is completed. All of the documents and materials generated during the study can be examined, including the data, field notes, codebooks, and other records. By following an audit trail, the external reviewer can determine if the research was conducted in a systematic and reliable manner.[4] Auditor, external reviewer, or external evaluator are not members of the research team nor the institution that conducts the research project; they are individuals that might represent the community or funding agency; many times they serve as external evaluators that verify the results of the study. Results of the audit trail or external evaluation might serve to impact policy, procedures, and make adjustments or refining of programs and training. The auditor verifies that the described research steps were actually followed.[5] Like tax records, research records should be retrievable and include dates. The auditor should be able to access raw data, communications, schedules, thematic summaries, and graphical representations of the interpretations.[6] Producing an audit trail enhances interpretation because researchers work with the data more than once.[4]

Summary

It is likely that healthcare research will continue to evolve and include more qualitative research approaches alongside the traditional study designs. The essential qualitative study described in this chapter provides an introduction to the way qualitative researchers may approach different questions in health care. By adhering to the basic concepts and steps discussed in this chapter, healthcare professionals can embark on their own investigations of the human experiences of their patients and others. Those not interested in conducting their own qualitative study will at least be familiar with the ways in which a qualitative study can be assessed. Healthcare professionals are advised to seek out supplementary explanations for the terms and methods discussed in this chapter. Mentors who are familiar with this type of research can provide additional assistance for those wishing to conduct their own qualitative investigation. Suggested readings that may provide clarification of the topics introduced in this chapter can be found in the Resources list at the end of the chapter.

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Resources

- *The Sage Handbook of Qualitative Research*, 5th ed., Denzin & Lincoln, 2017.
- *Qualitative Health Research: Creating a New Discipline*, Morse, 2012.
- Becoming a qualitative researcher, 5th ed., Glesne, 2016.
- *Culture and Meaning in Health Service Research: A Practical Field Guide*, Sobo, 2009.
- *On Knowing and Not Knowing in the Anthropology of Medicine*, Littlewood, 2007.
- *After a Fall: A Sociomedical Sojourn*, Richardson, 2013.
- *Assessing Information Needs and Use of Online Resources for Disease Self-Management in Patients with Rheumatoid Arthritis: A Qualitative Study. Clinical Rheumatology*, Des Bordes, Gonzalez, Lopez-Olivo, Shethia, Nayak & Suarez-Almazor, 2018, 1–7.
- *Participants' Perspectives of a Culturally Competent Diabetes Education for Hispanic/Latinos. Californian Journal of Health Promotion*. Peña-Purcell, Gonzalez, Garcia & Jimenez, 2014, Volume 12, Issue 2, 1–12.
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CHAPTER 9

Community-Based Participatory Research

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CHAPTER OVERVIEW

Despite the strides made to improve the overall health status in the United States, not all communities are benefiting equally from current medical and health advances. In fact, many of the complex health problems that persist in the United States have proven to be ill-suited for traditional "outside expert" approaches to health research, health improvement, and intervention development and implementation.[1-8] To decrease the growing gaps in health status among vulnerable communities such as minority (e.g., racial/ethnic communities and sexual minorities), economically disadvantaged, and other underserved communities, alternative approaches to medical and health research, health promotion, and disease prevention are being explored and promoted. Community-based participatory research (CBPR) is an approach to research designed to promote community and population health through the establishment and maintenance of community partnerships.[5-9] A partnership approach to research involves and benefits lay community members, representatives from community-based organizations (CBOs) and health departments, and medical and health researchers alike. Partnerships enhance both the quality of data collected and the validity of findings and their interpretation.[2-11]

In this chapter, we define and describe the advantages and processes of CBPR. We also describe why CBPR is an appropriate approach to research. We then introduce four research methods and describe how a CBPR approach may be applied and incorporated. Finally, we offer a case example of the application of CBPR in a behavioral research study.

LEARNING OBJECTIVES

- Define and describe community-based participatory research.
- List and discuss research paradigms.
- Describe common research methods used.
- Define, describe, and discuss four CBPR study designs.

Introduction

Community-Based Participatory Research Defined

Emerging evidence suggests that through a process of partnership that includes lay community members, organization representatives, and researchers, advances in health status and reductions in health disparities can occur as health promotion and disease prevention approaches, strategies, and efforts increase in authenticity. Lay community members and organization representatives participate in the research process to provide insight into the knowledge generated, guide the study and intervention design, ensure the accuracy of measurement, and support the interpretation of results. However, the partnership is not easy; researchers must establish and maintain trusting, authentic co-learning partnerships with community members if partnerships are to function well and improvements in health are to occur within communities, especially within the most vulnerable communities.[6-8,12-14]

CBPR (see **BOX 9.1**) is an approach that ensures community participation in research. CBPR establishes structures for full and equal participation in research by community members (including those affected by the issue being studied), organization representatives, and researchers to understand and improve community and population health and well-being through multilevel action, including individual, group, community, policy, and social change.[7,8]

BOX 9.1 CBPR

CBPR is a collaborative research approach that is designed to ensure and structure participation by communities affected by the issue being studied, by representatives of organizations, and by researchers in all aspects of the research process, from conception, study design and conduct, data analysis and interpretation, to the dissemination of findings.

CBPR emphasizes co-learning and the reciprocal transfer of expertise, decision-making power, and the ownership of the processes and products of research. This approach involves a strong partnership in which all parties (e.g., lay community members, organization representatives, health department representatives, and researchers) participate and share control over *all* phases of the research process. These research phases typically include:

1. Identifying research questions
2. Assessing community strengths, assets, and challenges
3. Defining priorities
4. Developing research and data collection methodologies
5. Collecting and analyzing data
6. Interpreting findings
7. Disseminating findings
8. Applying the results to address community concerns through action or intervention

Although the participation of the affected community in all research steps is critical to CBPR, another hallmark of CBPR is the translation of findings into action.[6-8] The accumulation of knowledge is important for the progression of science and understanding; however, the priority for most community members and organization representatives is the application of findings to improve the health status of community members, including friends, neighbors, families, consumers, patients, and clients. Furthermore, growing concern exists that the pendulum has swung too far toward “research for research’s sake” without the application of new knowledge to affect change to improve the health outcomes of populations and community members.[3,10,12]

CBPR relies on community participation to ensure the research questions asked are important not only to the researcher for the generation and accumulation of knowledge, but also to lay community members themselves. CBPR also helps to ensure the methods used are reasonable and authentic to existing community structures and experiences and are as noninvasive as possible. Finally, the increased validity of findings from CBPR yield more effective actions and successful

TABLE 9.1 Advantages of Community-Based Participatory Research (CBPR)

- Enhances data relevance, usefulness, and use
- Improves the quality and validity of the research by blending local knowledge and local theory based on the lived experiences of community members, expertise from organization representatives, and scientific perspectives
- Recognizes the limitations of the concept of value-free science and encourages reflexive and critical thinking among all partners
- Recognizes that knowledge is power, and thus knowledge gained can be used by all partners to direct resources and influence policies that will benefit the community
- Reduces the separation of the individual from her or his culture and context
- Aims to increase the health and well-being of the communities involved, both directly through examining and addressing identified needs and indirectly through increasing power, control, and skills (e.g., capacity building)
- Joins partners with diverse skills, knowledge, expertise, and perspectives to address health
- Strengthens the research, program, and problem-solving capacity of all partners
- Creates theory grounded in social experience, and creates better informed and more effective action guided by such theories
- Increases the possibility of overcoming the understandable distrust of research by communities
- Has the potential to bridge "cultural gaps"
- Involves communities that have been marginalized on the basis of, for example, race, ethnicity, class, gender, and/or sexual orientation in examining the impact of marginalization and attempting to reduce or eliminate it

interventions to positively affect health and well-being because of the inherent insights that emerge from partnership. **TABLE 9.1** illustrates the advantages of using a CBPR approach, as summarized from the literature.

Research Paradigms

All research approaches, including the design of a study and the methods selected, reflect a specific research *paradigm*. Research paradigms are defined as a set of fundamental beliefs about the nature of reality that can be studied and understood.[15] These basic beliefs are accepted merely on faith; however well argued, no way exists to establish their ultimate truth. The *positivist* and *postpositivist* research paradigms, for example, hold that a single reality on how things really are and really work exists to be studied and understood. The *positivist* research paradigm posits that this single reality can be fully captured; this paradigm is reflected in *experimental* research designs and methods, which are used most often in the basic sciences. In contrast, the *postpositivist* research paradigm holds that this single reality can only be *approximated*; human knowledge is based not on absolute "truths," but rather on human supposition. Postpositivism often is reflected in *quasi-experimental* research designs and methods frequently used in the social and behavioral health sciences. Both experimental and quasi-experimental methods require the goal of objective detachment between researchers and participants so that any influence in either direction on what is being studied can be eliminated or reduced.

CBPR is often aligned with a *constructivist* research paradigm, which holds that multiple realities exist to be studied and understood.[15] Each reality is an intangible construction rooted in people's experiences with everyday life, how they remember them, and how they make sense of them. Individual constructions of reality are assumed to be more or less "informed," rather than more or less "true," because they are always alterable. This means that as researchers and participants encounter and consider different perspectives, they will alter their views. The result is a *consensus construction of reality*[15] that is mutually formed by variations in preceding constructions (including those of the researchers), and that can move both participants and researchers toward communicating about action, intervention, and change.[16] The methods of constructivist research require researchers and participants to be interactively linked so that the consensus construction of reality is literally created as the study proceeds. Researchers using a CBPR approach are cast, therefore, in the dual roles of participant and facilitator.

Principles and Values of CBPR

Successful use of CBPR relies on various partnership principles and values[17-19] that tend to include:

- Mutual respect and genuineness
- Establishing and utilizing formal and informal partnership networks and structures
- Committing to transparent processes and clear and open communication
- Roles, norms, and processes evolving from the input and agreement of all partners
- Agreeing on the values, goals, and objectives of research and practice
- Building upon each partner's strengths and assets
- Offering continual feedback among members
- Balancing power and sharing resources
- Sharing credit for the accomplishments of the partnership
- Facing challenges together
- Developing and using relationships and networks outside of the partnership
- Incorporating existing environmental structures to address partnership focuses
- Taking responsibility for the partnership and its actions
- Disseminating conclusions and findings to research and clinical audiences, community members, and policymakers[6-8,17]

Often, the researcher feels that she or he must make decisions on behalf of the community. This is a natural inclination given the years spent in school, in training programs, and/or in the field. The researcher may be highly motivated to apply and use her or his resources for the benefit of the community. After all, the researcher is armed with intellectual resources: training and experience in the reduction of bias and the traditional approaches to increase validity with the hope of increasing generalizability; and perhaps financial resources or, at the minimum, increased access to financial and material resources to conduct research (e.g., grant funding and students), among other tools. Thus, the researcher may forget that community members and organization representatives have perspectives that are key for inclusion during the research process.

For community members, the textbook of life is living. With this axiom in mind, researchers must recognize that lay community members have perspectives that can significantly enhance all phases of the research process. Community members have firsthand knowledge of the health issue of concern. They can contribute to identifying and understanding the most salient health needs of their community; giving context to epidemiological data; and building a local theory about needs, challenges, and potential solutions that may not have occurred to or may not be readily understood by outsiders (e.g., researchers and other health professionals). Each of these points can strengthen research and intervention design through the interpretation of data and the development, revision, and evaluation (and further revisions if warranted) of intervention strategies.

Although their training and experiences may or may not have been learned in formal educational programs, organization representatives who are on the "frontlines" also have an understanding of the community that is not readily available or apparent to the researcher. They know how systems (e.g., service provision) are organized and utilized and may have a wealth of experiences providing services to community members on the frontlines or at the "grassroots" level. However, their perspectives may lack detail, and they may miss insights that have not been well discovered or explored.

Many researchers might conclude that they are on the frontlines in their capacity as health professionals (e.g., clinicians, counselors, health educators, pharmacists, providers of medical and mental health services, therapists, and other service providers); yet, they may genuinely know very little about the lived experiences of their patients or clients, especially the lives lived after patients or clients leave the office. To illustrate, having access to care and medications does not ensure that a patient will adhere to prescribed medication regimens for diabetes management. Patients and clients (and providers themselves) live in complex social contexts that cannot be easily understood or teased apart by outsiders. Thus, although organization representatives (e.g., individuals from community agencies like the health department, community clinics, agencies, etc.) may have useful knowledge, experiences, and theories, their insight alone is insufficient.

Four Study Designs

CBPR can be infused into any research methodology; however, the following section highlights four research methods and briefly outlines how CBPR can be applied to each. These methods are action-oriented community diagnosis (AOCD), focus groups, photovoice, and in-depth interviews. Although this discussion is not meant to be exhaustive, it is meant to serve as a starting point for researchers who want to explore the use of CBPR within qualitative research.

Action-Oriented Community Diagnosis (AOCD)

The purpose of AOCD is to understand the health status, the collective dynamics, the functions of relationships within a community, and the interactions between community members and broader structures that can impede or promote the conditions and skills required to assist community members in making decisions and taking action for social change and health status improvement.[4] AOCD can be a critical first step in program planning, intervention development and implementation, and evaluation because it provides the foundation for:

- The establishment of baseline data from which objectives, intended outcomes, and measures of change can be derived
- The selection of intervention methods and delivery that are most appropriate based on the community's structure, including formal and informal power dynamics and community assets and strengths
- A collaborative relationship between professionals and communities, who can begin "closing the gap between what we do not know and what we ought to know"[4,20]

AOCD may serve as a process for *needs assessment* (**BOX 9.2**) but goes beyond traditional interpretations of needs assessment. Although needs assessment is defined as a systematic examination and appraisal of the type, depth, and scope of needs to set priorities, AOCD also identifies and explores community assets on which intervention can be based. Philosophically true to CBPR, AOCD utilizes a *strengths-based approach* to research to identify both the needs and challenges faced by communities and just as importantly, the assets and strengths within the community. To forego the identification of community assets and strengths is to use a *deficit-based approach* that may miss key information vital to understanding the community's reality and lived experience and the strengths and resources on which successful intervention strategies can be based.

Like all research methods that adhere to a CBPR approach, AOCD begins with the establishment of a collaborative working relationship with community members. Representatives from the community, CBOs, and researchers come together to determine a research plan. Typically, existing community-specific data are reviewed. These data may include epidemiological data usually available from public health departments at the local or state level as well as other reports and resources

BOX 9.2 Needs Assessment

Needs assessment is the systematic examination and appraisal of the type, depth, and scope of needs to set priorities. It is the process of identifying and measuring gaps between what is and what ought to be.

available from local CBOs such as faith-based service providers and other agencies.

A *windshield tour* of the community can be an important initial step in the AOCD process. If the community consists of a geographical location, a researcher will explore the community guided by community members to gain an appreciation of the community's geography, size, physical characteristics, and important community venues (e.g., a corner store where people gather or a house of worship). This windshield tour is meant to be an introduction to a geographic community or a community of identity and its context through simple observation and community member guidance and commentary. If the community is less geographically defined—such as a community of elderly shut-ins, for example—a windshield tour may include the agencies and organizations that visit and offer support to these community members. A windshield tour for a virtual community might include exploring the chat rooms, mobile applications, listservs, bulletin boards, and newsgroups visited and used by the community and visiting sites that are advertised on pop-up and pop-under screens.

After the windshield tour and throughout AOCD, researchers document their experiences using *field notes*. Frequently kept in various study methodologies and often informal, field notes document details about the community that are interesting or noteworthy. When combined with other data, field notes might well prove to be significant. Field notes may serve several purposes:

- Provide the opportunity to document first impressions about a community
- Assist the researcher to remember experiences encountered in the field
- Record names of individuals and places that may prove key in the execution of the AOCD process
- Document unusual characteristics within a community

Field notes also allow the researcher to track her, his, or their perspectives, impressions, feelings, and frustrations during the AOCD research process. Field notes can be simply reflective writings while the research "event," such as a windshield tour, is still fresh in the mind of the researcher. It is wise to keep field notes of all research efforts because field notes serve as a documentation source for decisions made that affect the research process and subsequent data interpretation.

Because researchers tend to be very different from the communities they study, researchers need to gain an *emic* or insider's perspective on how people live and the issues facing the community.[4,6,21-24] An insider's perspective is privileged knowledge that only members of a particular community have. Outsiders can guess and hypothesize, but those assumptions are not value-free and may not be accurate or complete. Because no researcher can completely remove her- or himself from their research, an emic perspective provides the researcher insight into the perspectives of community members. For example, a homeless individual understands aspects of the lived experience of homelessness better than any outsider. Members of a disabled community can provide insights that may not be understood or correctly interpreted by an outsider.

Of course, some researchers may have started out as members of the communities they study and assume themselves to be insiders. However, the years of training in research methods and/or their content specialty and time outside of the community transform them into outsiders. In fact, outsiders who were once insiders may assume understanding that in fact is misunderstanding.[4,25]

Furthermore, one's social position in a community affects the "truth" of the experience of community life. For example, all African American gay men do not share a truth; in fact, among other influences, the perception of truth is affected by the position within the community. Thus, AOCD allows for distinctions and differences to emerge that may be lost through other approaches such as quantitative approaches. However, these emerging distinctions and differences challenge researchers who must work with community members to merge varying—perhaps contradictory—data and perspectives and make useful sense of findings.

Although the emic perspective is important, a hallmark of ACOD, and in fact, CBPR, is to move toward change through some action or intervention. Action may include, for example, a behavioral intervention to promote medication adherence or a policy change to increase access to medical or health care. Such movement also requires an understanding of *etic* or outsider perspectives. Outsiders are comprised of representatives from CBOs and other service providers such as those from the local public health department and may include health professionals (e.g., clinicians, counselors, health educators, pharmacists, providers of medical and mental health services, therapists) and other researchers. Outsiders provide perspectives on the health and well-being of communities, their access to resources, and community strengths, as well as support for subsequent action or intervention. Like community members themselves, outsiders have a story to tell based on their experiences.

After reviewing and incorporating secondary or extant data and collecting, analyzing, and interpreting emic and etic data in partnership with community members and organization representatives, the researcher helps the community disseminate the findings. AOCD relies on a *community forum* to present the findings of a research process to *influential advocates* (e.g., local policymakers, service providers, healthcare providers identified by participants as potential collaborators and advocates for change). This forum highlights issues and possible solutions for the community. The forum allows the community to dialogue with influential advocates who are supporters, but who may also benefit from increased awareness and greater understanding of the situation. The forum is an opportunity to initiate dialogue and come together during a facilitated discussion to explore potential action or intervention.[17,26] Without the forum, AOCD merely explores causes but does not move to improving the health status of the community. Dissemination of findings within the community and movement toward action are important steps in both AOCD and CBPR.

AOCD requires the involvement of both insiders and outsiders to ensure the collection of accurate (defined as reliable and valid) data and the correct interpretation of these data. AOCD might include understanding both the emic and etic perspectives of uninsured families within a cultural and geographic community. This understanding may lead to action and, perhaps, policy changes that reduce barriers and/or increase access. For example, monolingual Spanish-speaking Latinos may have little access to public health department services if their local health department does not have translation capacity. A forum can educate providers on the ramifications of the deficiency and spark new ideas and innovative approaches to solving problems. AOCD allows for solutions to emerge based on the compilation of realities that come from various perspectives. No one group or sector is responsible for change; rather, direction and change come from a negotiated process that includes multiple groups or sectors. The exchange of perspectives and ideas allows insiders and outsiders to see community health from fresh perspectives and builds partnerships that are stronger and can move forward in directions that positively affect health.

Often emic and etic perspectives are explored and interpreted through the use of qualitative methods. A CBPR partnership may choose to conduct focus groups, photovoice, or qualitative interviews—methodologies that also are outlined in this chapter. More quantitative methods may be less useful during the early stages of AOCD because they may not allow for sufficient flexibility and exploration of perspectives. However, they may provide important data in less exploratory or developmental research. Moreover, researchers, and in fact, community members and organization representatives, often assume that CBPR requires the use of qualitative approaches. However, CBPR is useful during all phases of quantitative and mixed methods studies as well, including intervention outcome evaluation studies.[6,8,25,27-31]

Focus Groups

As a qualitative methodology, focus groups provide the opportunity to investigate participant responses and reactions related to an issue or topic more fully. They also allow new areas of inquiry to emerge. The methodology can reveal key nuances and perspectives that clinician researchers may not be able to foresee.[4,32-34] Briefly, focus groups usually are composed of 6 to 10 participants who are guided through a set of general predetermined open-ended questions outlined in a *focus group moderator's guide*. The guide may be based on behavioral theory[35,36] or may allow for the theory that explains a phenomenon to be developed based on the findings, much like a *grounded theory* approach to research.[17,24,37] Either way, the guide should be agreed upon by the partners. Not only should the research objectives be mutually agreed upon, but the selection of focus groups as a methodology and the line of inquiry outlined within the guide should reflect the most meaningful approach and language as agreed upon by the research partners.

After an introduction to the focus group process (and of course getting informed consent to participate) as well as outlining ground rules (e.g., speaking one at a time, respecting various opinions, and maintaining confidentiality), the participants, who sit in a circle, respond to open-ended questions. Group interaction is an explicit component of this methodology. Instead of the researcher asking each person to respond to a question, in turn, participants are encouraged to talk to one another, asking questions, exchanging anecdotes, and commenting on one another's experiences and perspectives.[17,32,35,36,38] The moderator must be skilled and experienced in soliciting discussion from all participants in a group, reminding participants that there are no wrong answers, affirming all opinions, and probing for detail. Probing for detail, whether through examples, clarification, or further exploration, is key to successful qualitative data collection, especially when using focus groups. In most cases, qualitative research requires the researcher to allow the design to emerge more fully during the project's evolution;[39,40] thus, all potential questions cannot be predicted. The moderator's guide is meant to serve as an outline, but the moderator must facilitate the discussion beyond what is written within the guide. The moderator may need to probe into a perspective to develop and understand it more thoroughly. However, the moderator must be skilled at keeping the discussion on track. If the discussion deviates from the purpose of the focus group, the moderator must be able to bring the discussion back to the purpose.

In addition to a moderator, successful focus groups most often involve at least one *note taker* who documents participant speaking order, body language, and facial expression that cannot be captured by audio recording. These details may provide valuable insight during the data analysis and interpretation phases. Because anonymity may be desired, names of participants may not be used; rather, participants may be assigned numbers that are added to the focus group transcript to track which focus group participant is responding. It may not be essential to know the name of a participant; however, it may be important to attribute certain quotations to certain participants. Perhaps only one participant has a certain perspective about a topic that she or he continues to reiterate. When analyzing the transcripts, it may be important to recognize this and weigh the findings accordingly.

The note taker also documents nonverbal communication. If a participant is noticeably uncomfortable with a discussion topic or the focus group discussion but does not assert her or his unease or disagreement, such observations should be noted by the note taker. Overall, the note taker is documenting what is going on during the focus group session that may be missed by the audio/digital recorder and by the moderator who is leading the session.

When applying a CBPR approach to focus group research, the research question, moderator's guide, and recruitment methods must be developed and agreed upon by the research partners. Data analysis and interpretation should be completed in partnership to allow for community participation.[5]

Photovoice

Photovoice is a qualitative method of inquiry that:

- Enables participants to record and reflect on their personal and community strengths and concerns
- Promotes critical dialogue and knowledge about personal and community issues through group discussions and photographs
- Provides a forum for the presentation of the lived experience of participants through the images, language, and contexts defined by participants themselves[26,41-45]

As a method closely aligned with CBPR, photovoice improves the quality and validity of research by drawing on local knowledge, developing local theory, and progressing toward action. Perhaps one of the most participant-driven research methodologies, photovoice engages participants in the following procedure:

1. Attend a training session to receive a disposable camera, and determine the topic for their first photo assignment.
2. Record through photography each photo assignment.
3. Share and discuss their photographs from each photo assignment during photo discussion sessions.
4. Organize a forum to present their photographic and thematic data to *influential advocates*.
5. Create plans of action.[44]

Photo discussions typically begin with a review and discussion of themes that emerged from the analysis of previous sessions followed by a "show and tell" activity that allows each participant to share her or his photographs and explain how the photographs relate to the photo assignment. These discussions often follow a Paulo Freirian–based[46] model of root-cause questioning and discussion known by the acronym *SHOWED* (see **BOX 9.3**).[45,47,48] However, because SHOWED has proven to be unwieldy at times,[48] other guides or triggers are used. For example, a simpler approach has been effectively conducted using: (1) What do you see? (2) How does this make you feel? (3) What do you think about this? and (4) What can we do?[45] A Spanish-language version of SHOWED also has been developed and used.[49]

BOX 9.3 SHOWED

SHOWED follows the following discussion outline:
What do you *see* here?
What is really *happening* here?
How does this relate to *our* lives?
Why does this concern, situation, or strength exist?
How can we become *empowered* through our new understanding?
What can we *do*?

At the conclusion of each photo discussion, the group develops a new photo assignment by asking, "Given what we have learned so far, what should we explore next?"

The photo discussion data are analyzed like other qualitative data, through exploring, formulating, and interpreting themes. The participants share these themes with local community leaders, service providers, and policymakers. These photographs serve as the medium through which issues are discussed to raise awareness among a core group of allies, mobilize these allies, and plan for change.

Photovoice transitions from knowledge, or raised consciousness around issues and assets, to direct community action. Although a relatively new methodology, photovoice has been found to be a flexible method both regarding the issues it explores and in relation to the geographic and culturally diverse groups. It has been applied in partnership with a number of communities including Latino youth in the rural southeast;[48] women in Yunnan Province, China;[50,51] homeless men and women in Michigan;[51,52] heterosexual immigrant Latino men;[42,45] youth peer educators in Cape Town, South Africa;[53] urban lay health advisors;[10] HIV-positive persons;[26,43,54] and public health department leaders and constituents.[55]

Individual In-Depth Interviews

Individual in-depth interviews are another common data collection methodology. These interviews are *unstructured*, *semistructured*, or *structured* depending on the research goals. Unstructured interviews are characterized by questions that emerge during the interview process. The research partners may have general topic areas or categories, but the questions are asked as they are formulated in the natural course of the discussion. There is no predetermined wording of questions. This style is more conversational and increases the salience and relevance of questions. A problem with unstructured interviews is that different information is collected from different individuals based on different questions. Unstructured interviews may be useful for initial explorations or case studies. However, unstructured interviews can result in less systematic and comprehensive data, causing challenges in data analysis.

Semistructured interviews by definition provide more structure for the interviewer. Topics and issues to be explored and discussed are specified in advance, often in outline form. Semistructured and structured interviews require an *interview guide* that leads the interview process. Leading a semistructured interview, the interviewer often decides the order and sequence of the questions during the interview. The interviewer may probe for detail and develop questions and their wording during the interview process. Data collection using this approach is more systematic than an unstructured approach. Because semistructured interviews remain conversational and situational, gaps in data can be explored and closed. However, important and salient topics may be inadvertently omitted as interviews go in directions that jeopardize comparability among interviews and the data collected.

Structured interviews are often well defined before the interview. The sequence and exact wording of questions are determined in advance. All interviewees are asked the same fundamental questions in the same order and manner.

Interview questions may be *open-ended*, *closed-ended*, or a combination of question types. Open-ended questions tend to provide more exploratory, developmental, and contextual data. Data from open-ended questions tend to be more descriptive. For example, an open-ended question that was asked of healthcare providers who worked in an undocumented Latino community was: "If you could envision an answer to meeting the healthcare needs of the local Latino community, what would that vision be?" Answers were descriptive and elaborate, providing not only ideas about how to meet healthcare needs in the short- and long-term, but also further information about what healthcare needs existed in this community and root-cause explanations and insight into the sociopolitical context about health.

Closed-ended questions are characterized by response options that are *fixed*. Participants choose among a list of fixed responses. An example closed-ended question from a structured interview implemented among Latino men was: "Some men report having sex with other men for a variety of reasons; have you ever heard of a male friend having sex, including oral or anal sex, with another man?" The response options were: "yes," "no," and "refused to answer."

Closed-ended response options simplify data collection and analysis because many questions can be asked in a shorter period and responses can be easily aggregated and compared. The disadvantage, however, is that participants must fit their experiences and feelings into predetermined categories. This may distort the true experiences and feelings of the participants by limiting their response choices. Closed-ended questions and responses may also reduce participants' ability to express why and the context of the phenomenon of interest.

Conventionally, closed-ended interviews collect data on a topic by asking individuals questions to generate statistics on the group or groups within a community or population that those individuals represent. Closed-ended interviews do not tend to be formative or exploratory; rather, they ask questions about a variety of factors that influence, measure, or are affected by health. For example, population-based or community-wide, closed-ended interviews may document and follow health status. Alternatively, closed-ended interviews may provide local data and a baseline for evaluation of intervention efforts. After a local CBPR research project has evolved and developed a research intervention to effect change (e.g., individual behavior change, community change, or policy change), interviews comparing baseline data to intervention implementation or postintervention follow-up may provide information on how well the intervention is working.

When applying a CBPR approach to research, the research question, measurement method (e.g., interview, questionnaire), and items or questions to be included must be agreed on by the partnership. Furthermore, the process of recruitment and administration must be decided by the partnership. Basic questions the CBPR partnership will want to answer as members prepare a study include:

- How will participants be recruited?
- What type of compensation will be provided?
- Who will administer the interview or questionnaire?
- Will interviewers be used or will the questionnaire be self-administered?

Researchers may think they know the best way to recruit interviewees and administer data collection procedures; however, community partners may provide great insight that may increase recruitment and response rates as well as honesty in responses.[56,57] In fact, what seems scientifically sound to the researcher (e.g., reducing bias and threats to validity) may inhibit responses.

Qualitative and Quantitative Data Analysis

Analyzing and interpreting any type of dataset, whether qualitative or quantitative, using a CBPR approach is challenging. Ensuring the participation of all partners in the process can be daunting. Researchers may have a variety of data analysis software to choose from that community partners may not have the time or energy to learn and apply. Thus, creative ways to examine data may be necessary. During qualitative data analysis, community partners may review and provide perceptions on potential themes through their detailed reading and rereading of the transcripts separately. The researcher may choose to analyze the data using a software program to code and retrieve non-numeric data (e.g., NVivo, ATLAS.ti, Ethnograph, NUD*IST, and Dedoose). Coming together, the research partners compare broad categories, resolve discrepancies, and begin the process of interpreting the findings through the development of themes. Themes based on qualitative data are most often directional. Themes can be described as potential assertions that can be tested later through subsequent research. Examples of themes developed using qualitative analysis include: (1) Manhood is affirmed through sex.[17] (2) Undocumented Latinos felt that they have no right to access public health care.[58] (3) Familiar brand-name medicines are preferred by immigrants.[59] Quotations are usually abstracted from the qualitative transcripts to illustrate the themes.

Quantitative data analysis poses similar challenges.[5] How can community members, who lack quantitative data analysis skills or software training, participate in this phase? Researchers should communicate and solicit feedback from the partners throughout the process, keeping them up to date on statistical approaches, decisions, and rationales. Furthermore, researchers should not assume that partners do not want to be engaged in the analysis process.[5] After all, CBPR promotes knowledge gain and skill development on all sides. As mutual co-learners, the researcher is learning about the partners, and the partners are learning as well; this learning may include building data analysis skills.

Because it may be difficult to ensure participation of all community partners, getting a commitment from one, two, or three partnership members who are from the community may be key to the data analysis.[5] The entire CBPR partnership may not choose to participate in all phases of the research process, but establishing guidelines that ensure community member representation in each phase of the process is key.

In this section, only a few research methods were described. However, it is important to note that a researcher need not give up traditional research methods, but may infuse a CBPR approach into any research method.

▶ Initiating CBPR

Beginning the exciting work of CBPR requires a clear understanding of partnership principles and values, as outlined earlier in this chapter. In the following sections, we outline some pivotal tasks in the researcher's effort to engage in CBPR.

Network, Network, Network

A first task in the CBPR process requires the development of a network with other individuals with a similar health area of interest or concern. A relatively easy and helpful initial contact for a researcher may be a local public health department. Providers and educators within health departments around the country are likely to have connections with community agencies working with those affected by and committed to a variety of health concerns. A clinician, administrator, nutritionist, intern, health educator, and/or epidemiologist within the public health department might already be working with established local health coalitions or community groups. Dialoguing with these potential partners represents a good solid start in this process and is well worth the effort. A simple review of a public health department website or a telephone call to the health department may offer initial guidance and contacts, and an informational interview with a health department staff member will begin the networking process essential throughout CBPR. As a researcher, casting a wide net facilitates networking contacts to identify overlapping health concerns and resources, including talent that may support the research process synergistically. Networking also initiates the establishment of trust that is key to success in CBPR.

The researcher must understand the local communities and work in collaboration, not through confrontation, with local *stakeholders*. Stakeholders typically are individuals who are affected by the health issue and those who will be part of the research as well as affected by the research and subsequent change. Stakeholders may include community members experiencing the problem, service providers, and community leaders, among others.

In addition to contacting and networking with a local public health department, making connections with those healthcare providers in the community who are working with individuals and community members affected by overlapping health and research priorities may provide access to potential partners. The researcher benefits from thinking broadly about those individuals providing care (e.g., counselors, exercise physiologists, mental health providers, nutritionists, physical therapists, etc.). Furthermore, becoming familiar with other local CBOs, other types of community agencies, and service providers and making contact with representatives from a variety of organizations will yield helpful results. The researcher may find partnerships for CBPR within the local school system, clinical settings, clubs and service agencies, and/or retirement communities, just to name a few more possibilities.

Build Trust

After commonalities have been identified, the researcher will begin a process of *trust building*. Trust building is especially important because communities have felt exploited as “living laboratories” for universities and medical centers. Often communities are inundated by research projects that test hypotheses but do not benefit the community itself through some type of action or intervention to improve and promote health and well-being. Communities may be apprehensive about committing to a partnership, and the researcher may have to overcome a history of research that was not initiated and conducted respectfully.[60] A positive relationship is built by working hand-in-hand with community members. A researcher may choose to spend some up-front time volunteering with a CBO and serving on local health coalitions. This level of commitment serves several purposes. First, it advances a genuine and mutually respectful relationship with key community leaders whom the researcher may need and want to have on board as partners in the research. It may also open other doors for the researcher; the researcher may be unfamiliar with all the players and may use the opportunity to identify informal community leaders who may be committed to a health issue and may be interested in the research. Third, it allows the researcher the opportunity to understand community structure, decision-making processes, and levels of influences through their role as a participant observer. Finally, community service allows community members to interact with the researcher in a setting that is not focused on any one agenda. By selecting the right place to volunteer and thus "be seen," the researcher may build community trust by association. If a Latino-serving CBO is well respected by the local Latino community, for example, the researcher will gain more immediate community favor, and thus participation, by spending time there. Such volunteer work not only builds trust, but also begins to offer emic and etic community perspectives to the researcher.

Building trust includes building relationships. Relationships among lay community members, organization representatives, and researchers may involve informal "working" meetings that allow partners to get to know one another. Community events such as street fairs, church gatherings, and forums as well as parties and celebrations are ideal places for lay community members, organization representatives, and researchers to convene. These types of opportunities show commitment to the community and allow for lay community members, organization representatives, and researchers to know one another better. This approach improves trust and communication, which improve the research process.

Maintain Relationships

Key to trust building is *relationship maintenance*. Although it may be easy to feel one has built trust, one must remember partnerships cannot be taken for granted. When things are being done behind the scenes, gaps in the research process may exist; the researcher must be present within the community. For example, getting a research protocol approved by an institutional review board (IRB) or ethics committee may require a delay in the research process, but the researcher must touch base with partnership members to provide informal status reports. This is important because the researcher does not want to lose community interest, motivation, or momentum. Community members do not necessarily understand the confusing steps required by universities, research institutions, and funders. Time should be spent in dialogue explaining these steps and their rationales.

Negotiate Partnerships

Subsequent tasks in the CBPR process include bringing key community members and organization representatives together. This may be easy if an existing community health coalition exists. The coalition can determine whether a health issue is of interest or not. If a health issue is not a focus, and yet data suggest that it contributes profoundly to morbidity and mortality of the community that the coalition serves or represents, the researcher has to walk a fine line between asserting what she or he perceives to be "important information" and staying true to the priorities of the community. Exploring community priorities and perspectives may yield important insight or even areas of overlap. It may require thinking creatively or "outside of the box." The researcher may provide data and increase awareness, affirming her or his agenda, or she or he may decide the community-prioritized agenda is important and an opportunity to build trust and relationships. Nothing can impede or destroy trust between a researcher and the community members and organization representatives more than going into a community to "fix" something without asking community members what they prioritize. After all, community members are not inanimate objects to be "fixed"; they are potential partners. CBPR requires the researcher to be flexible, and no place is this flexibility more evident than in adaptations related to community priorities. A researcher may be required to take on other priorities as identified by the community in the spirit of partnership.

However, the importance of linking community needs and priorities with researcher interests and skills cannot be ignored. Just as community priorities must be respected, researchers must be honest with communities about where their interests and skills overlap and complement. Researchers should not prioritize community priorities without regard to the epidemiologic data; in fact, community members and organization representatives may rely on researchers to provide that epidemiologic data and thereby provide a context for their perspectives. Thus, education and negotiation among community members, organization representatives, and researchers are warranted to establish priorities. Through iterative negotiation, these priorities are more informed. Without negotiation of priorities, it is unlikely that anyone will be effectively served or community health enhanced.

The researcher may begin with a community health coalition or may need to identify and build a network of community members and CBO representatives. Through this network, the foundation of a partnership may be established. Although growth may occur throughout, this network may evolve into a partnership through the hard work of those involved.

A Case Study

HoMBReS: Hombres Manteniendo Bienestar y Relaciones Saludables

HoMBReS, an acronym for *Hombres Manteniendo Bienestar y Relaciones Saludables* (Men Maintaining Wellness and Healthy Relationships), was an intervention research project in rural North Carolina that was initiated through a partnership of lay community members, organization representatives, and university health professionals and researchers.[5-8,13,28,31,61-63] A community health coalition known as Chatham Communities in Action (CCIA) was formed in 1991 as part of the North Carolina Community-Based Public Health Initiative (CBPHI).[6,36,64,65] Because of the rapidly growing Latino community in North Carolina and their early success in diabetes prevention within the African American community, CCIA, with expanding Latino membership, chose to explore Latino health concerns within their local community. A subgroup of CCIA members met with university researchers to develop a plan to explore the healthcare priorities of the Latino community.

The CBPR partnership, which initially was composed of members of CCIA, convened first to determine how to develop the CBPR partnership further to expand Latino representation. Local Latino-serving CBOs and interested individuals who were not involved with CCIA were invited to participate in the process. This inclusion required time to build trust and clarify goals. These added members included representatives from a local adult Latino soccer league, a local Latino *tienda* (grocery store), and a farm worker advocacy group. The soccer league was a nine-county Latino soccer league of over 1600 adult men. The league president, along with various other interested league members, became involved in the CBPR partnership. The research partners continued to build trust among themselves as research partners through personal relationships, genuineness, respect, and "being there." CCIA representatives and the researcher spent many dinners meeting with league representatives. Although CCIA had a history of working with the university, these relationships could not be assumed or taken for granted. Building and maintaining trust and communication always plays a paramount role in CBPR.

The expanded CBPR partnership gained consensus on the research aims. This process involved answering two equally important questions. First, the research partners had to ask themselves: "What do we want to know?" Second, the partners had to ask themselves: "Why do we want to know it?" This distinction is important because a CBPR approach recognizes that knowledge for knowledge's sake (i.e., the accumulation of scientific knowledge) is important, but the immediate application of knowledge to affect the health and well-being of the participating community is equally important. The researchers had many curiosities and theories they wanted to explore, but the partners kept the focus on the practical use of knowledge gain.

In this study, members of the CBPR partnership chose to explore health concerns of Latino men primarily because the majority of Latinos who had recently arrived in the United States were male, especially in rural North Carolina. Partners had to agree on the research and recruitment design and the roles and contributions of each of the partners. They decided to use focus groups to explore health priorities. Partners created, reviewed, revised, and approved the focus group moderator's guide. The league president recruited focus group participants, and two partnership members served as the focus group moderator and the note taker. The note taker was the university public health researcher, who was proficient in Spanish. A Latino-serving CBO hosted the focus groups. Seven focus groups were completed.[5,36]

The first stage of data analysis involved members of a subgroup from the CBPR partnership sorting the focus group transcripts into broad content categories. After the initial sorting process was complete, the analysis team came together to compare broad categories and begin the process of interpreting the findings into conceptual domains. After themes were created, the themes were presented to members of the CBPR partnership and other community members including soccer league members for *number checking* and interpretation. This was done by writing themes on flip charts and presenting these draft themes to the CBPR partners and representatives from the soccer league to review, discuss, and revise. Several iterations of this process were completed to ensure the validity of the interpretation of the data.

Findings were disseminated through community and national presentations, report writing, and manuscript development. Because action is a key component of CBPR, the findings also were used for funding proposals and intervention design. All partners had equal access to the findings. For example, organization representatives used preliminary findings for service grant and programmatic grant preparation, and community members used the findings to advocate for Latino men's health within the health department. It was through the initial focus groups that human immunodeficiency virus (HIV) and sexually transmitted disease (STD) infection were identified as priorities by members of the Latino soccer league, as well as the potential use of the social network of the league to develop, implement, and evaluate a social network lay health advisor intervention.[36]

The HoMBReS intervention study was funded by the Centers for Disease Control and Prevention (CDC). The goal of this CBPR study was to reduce the risk of HIV/STD infection among Latino men through the development, implementation, and evaluation of a lay health advisor intervention. Briefly, HoMBReS was a multiyear quasi-experimental research study with four interrelated objectives:

1. Develop and implement a lay health advisor intervention to reduce HIV/STD risk behaviors among members of the soccer league.
2. Evaluate the efficacy of the intervention by comparing soccer league members in the intervention to those in the delayed-intervention comparison group using self-reported sexual risk behaviors and utilization of HIV/STD counseling, testing, and treatment services.
3. Evaluate the changes experienced by the lay health advisors by being trained and serving as lay health advisors.
4. Assess the feasibility of engaging a soccer league in implementing a lay health advisor intervention designed to reduce HIV/STD transmission among Latino men.

The lay health advisors (based in the social networks of soccer teams), known as *Navegantes* (Navigators), were trained to provide HIV/STD prevention education, information, and service and resource referrals to their teammates. They served as: (1) sources of HIV/STD information and referral, (2) opinion leaders to change risky behavioral norms resulting from culturally infused male gender socialization, and (3) community activists to work with organizations such as the local public health department to better address the needs and priorities of Latino men in culturally congruent approaches.

This project was successful in the recruitment and training of a strong cadre of Navegantes because of the initial buy-in of the Latino soccer league. Without their history of interest, support, and involvement, the idea for HIV/STD primary prevention and the use of team members as lay health advisors would not necessarily have been considered or possible. Had it been considered, the risks would have been higher because buy-in would not have been garnered. Less knowledge about whether men would want to participate in a 16-hour, theory-based training and what that training should include would have left more opportunity for misjudgment on the part of the researcher. Instead, the partnership approach ensured fewer problems were incurred; when unavoidable roadblocks did occur, creative solutions that had a higher potential for success were explored because more perspectives and options were identified.[13,61,62,66]

The HoMBReS intervention was found to successfully increase condom use and HIV testing. At postintervention assessment, the intervention was found to have increased condom use and HIV testing among teammates in the intervention compared to their peers in the comparison control group.[28] Further, the success of this initial study that was conducted in partnership with lay community members and organization representatives has led to further interventions. The CBPR partnership developed a multisession small-group intervention designed to increase condom use and HIV testing among heterosexually active Latino men entitled *HoMBReS-2*, which in pilot testing was found efficacious.[29]

The partnership is currently testing two different interventions for Latino gay and bisexual men, men who have sex with men (MSM), and transgender persons. One intervention is a lay health advisor intervention entitled *HOLA*. This intervention is based on the original HoMBReS intervention; however, rather than utilizing the social structure of the soccer league, it harnesses informal social networks of Latino gay and bisexual men, MSM, and transgender persons. Lay health advisors, also known as Navegantes, are trained to work with their friends to increase condom use and HIV testing.[27] The second intervention is entitled *HOLA en Grupos*, a small-group intervention for Latino MSM, also designed to increase condom use and HIV testing.[14]

Since the partners began their intervention research with immigrant Latino men, Latinas (e.g., girlfriends, wives, partners, sisters, and female cousins of male participants) stepped forward and asked representatives of the CBPR partnership for HIV prevention programming tailored to their needs and priorities. Based on extensive formative research, partners developed a culturally congruent intervention entitled *Mujeres Juntas Estableciendo Relaciones Saludables* (*MuJEReS*), translated as Together Women Establishing Healthy Relationships. The intervention, which is designed to reduce the disproportionate HIV burden borne among Latinas in the United States, trains Latina lay health advisors, known as *Comadres* from the community, to work within their existing informal social networks. Latinas chose the term *Comadre* because of its common use to mean a trusted friend or neighbor who can be relied upon for advice and assistance. Besides the formal and informal health advising in which Comadres engage, partners determined that each Comadre also holds six 60- to 90-minute group sessions during intervention implementation with their social network members. These group sessions include (1) hosting a *fiesta* (party) to inaugurate the Comadre's role as a resource within her social network; (2) learning and practicing correct condom use skills; (3) brainstorming and discussing ways to overcome communication barriers with sex partners; (4) brainstorming and discussing ways to overcome communication barriers with providers; (5) demystifying the HIV testing process through describing available testing options, delineating the process (eligibility, etc.), and illustrating challenges that will be faced and how they can be surmounted; and (6) exploring what it is like to be an immigrant Latina through facilitated dialogue designed to build positive self-images and supportive relationships.[67]

Summary

It has been asserted that ensuring the health of the public will require clinicians, health professionals, researchers, and others to join forces with lay community members and organizations of both community insiders and outsiders to generate new understandings of health status, explore health status predictors and measures, and uncover innovative ways to effect change in the health status within vulnerable communities.[2,68] Although this may seem logical, the process of partnership requires time to establish trusted relationships, create a research infrastructure, and develop a history of partnership. The investment of time to build these trusted relationships is essential for successful CBPR; this effort is well worth the expense in time, energy, and resources if true changes in health status are to occur.

Although no road map exists to conduct CBPR, it is important to note that often individuals, including health professionals, researchers, and community members, who are unfamiliar with CBPR confuse *community placed* with *community based*. Community-placed efforts directly imply that clinicians, health professionals, practitioners, and researchers leave the traditional institutions such as the university, hospital, or medical center and go into the community to do their work. However, community-based efforts are more than going outside the physical walls of these traditional institutions. CBPR requires partnering with communities and basing efforts in reality and structures *preferred* by the community.

Health research through community partnership is a viable mechanism for health promotion and disease prevention[2,3,6,8,10,11,69,70] because CBPR improves the quality of research, increases community capacity, and advances positive health outcomes by:

- Bringing community members into a study as partners, not just as *subjects*
- Using the knowledge of the community to understand health problems, take appropriate action, and design meaningful interventions
- Connecting community members directly with how research is done and how it is used
- Providing immediate benefits from the results of the research to the community that participated in the study

CBPR can be infused into any research design. In this chapter, four methodologies were briefly presented, and one case study was described. Researchers who are exploring the use of CBPR in their research and practice should remember two important issues. First, key to using a CBPR approach is the inclusion of lay community members, CBO representatives, health department and other agency staff, and university personnel, including students and faculty researchers.[10] Together these partners, must share control over all phases of the research process, including community assessment, issue definition, development of research methodology, data collection and analysis, interpretation of data, dissemination of findings, and application of the results to address community concerns. CBPR recognizes that lay community members themselves are the experts in understanding and interpreting their own lives.

Second, inherent in CBPR is a commitment toward action or intervention. This action may be loosely defined, including community organizing and mobilization, the development of new and authentic community member and agency partnerships with concrete tasks, and measurable plans for action with assigned responsibilities and defined timelines. The actions may be focused on immediate changes to improve health-related conditions, such as changes in a clinical practice protocol that increases adherence to an AIDS medication, policies that increase access to community mental health services, or even improved lighting on an outdoor neighborhood running/walking track to encourage utilization. Furthermore, actions may be focused on long-term changes in social determinants of health, such as improved racial equality in administrative and political representation through community mobilization and organization.

CBPR not only may be an effective tool to address the complex health problems facing vulnerable communities but also is considered to be a just and democratic approach to research, as has been noted by community members. "Nothing about me, without me," implies that community members have a *right* to participate in all aspects of the research endeavor. Although CBPR is a challenging approach to research, it offers the researcher the opportunity to participate in a co-learning process of sharing resources, knowledge, skills, and attributes to increase the quality and validity of the research. Increased quality and validity thus yields more effective interventions and improved health outcomes.

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CHAPTER 10

Clinical Investigations

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CHAPTER OVERVIEW

Clinical studies are invaluable to health care. This is where laboratory research is translated into patient care. Healthcare organizations are becoming engaged with clinical research to generate income. Many healthcare providers are finding themselves involved with clinical research without much prior experience. This chapter provides an introduction to clinical research.

LEARNING OBJECTIVES

- Define *clinical investigation* and the phases of clinical research.
- Discuss and describe clinical investigation design and methodology.
- Describe subject selection.
- Define and describe *informed consent, adverse events*, and *study termination*.

Introduction

Increasing public demand for new Food and Drug Administration (FDA)-approved medications and medical devices has generated an increase in clinical research. The overall goal of clinical research is to maintain the safety of the research participant while determining the efficacy of the investigational product. Clinicians are becoming more involved in clinical research studies as principal investigators, sub-investigators, or study coordinators, whether voluntarily or involuntarily assigned such a role. This chapter provides a basic introduction to the clinical research process by describing the phases of clinical research, discussing subject selection and protection, as well as describing the informed consent process, adverse events (AEs), and study termination.

The Clinical Research Process

Healthcare providers may be asked to participate in a clinical research study as a study coordinator. This may be a request, or the role may be assigned by the practice's administrator. Most clinical research studies are conducted in the same manner, whether it is a sponsored pharmaceutical investigation, a medical device study, or benchmark research from an academic institution. Whatever the setting, research processes are somewhat standard.

When conducting any clinical research, the most critical aspects are (1) to ensure that the research participants have a complete understanding of the research study, and (2) to protect the participants at all times throughout the study. A specific guideline, known as the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) *Guideline for Good Clinical Practice (GCP)*, maintains that every research participant must be completely informed of the study they are about to enter. Being completely informed means understanding the study expectations, potential risks, and potential side effects, as well as how the research site and sponsor (and/or institution) will fully monitor their progress throughout the study. Because healthcare professionals of all types may be asked to assist with a research study in their practice (or even invited to be the study coordinator), the information in this chapter provides a general idea of what to expect when working with most clinical research studies.

Understanding the key personnel roles involved in clinical research is essential. A clinical research study will always identify a principal investigator (PI). The PI is typically a physician who assumes total responsibility for the entire study. The PI is, therefore, responsible for the welfare of the study participants—ensuring that study subjects have been adequately informed, have given consent, and have met the study's inclusion and exclusion criteria. The PI also oversees any AEs and manages subsequent outcomes. The PI is responsible for all personnel involved in the study: sub-investigators, study coordinator(s), medical technicians, and practitioners. The PI must ensure each person involved is qualified to perform his or her designated role in the study. For instance, an inappropriate assignment of a study responsibility would be delegating a medical assistant to perform a physical exam on a research patient. Therefore, the PI role is a solemn responsibility. The PI answers for any violations that occur throughout the course of the study.

The PI may choose to designate a sub-investigator (sub-I) or co-investigator to help oversee the research study at the site. A sub-I is especially helpful when a research study is being conducted at satellite clinic locations. The sub-I may be located at a different clinic than the PI and, therefore, can assist in the follow-up of any research participants that are being seen at that particular clinic. Most sub-Is are physicians as well; however, other healthcare professionals or doctoral-level researchers, such as PhDs, can also serve in this role. Sub-Is typically hold some form of medical licensure, and this role involves responsibilities similar to those of the PI. However, the PI retains the sole responsibility for the entire research study and research personnel, including the sub-Is.

The study coordinator is the central person in a research study and is highly involved in the research process. Most study coordinators are registered nurses; however, other healthcare professionals are being asked to assume the role of study coordinator in spite of their busy clinic schedules. The study coordinator's role is vital to the entire project. Most site personnel who are asked to be the study coordinator for a clinical research study are often surprised at the amount of work (or additional work) this role entails. The study coordinator's primary responsibilities include the following:

- Recruiting subjects for the study
- Explaining the research study to the patient and answering any questions
- Reviewing and obtaining the patient's informed consent
- Ensuring all of the study entry procedures have been conducted
- Reviewing the study's inclusion/exclusion criteria with the PI and/or sub-I to verify the patient's eligibility
- Documenting the study visit information on the case report forms (CRFs), either transcribing the data onto paper CRFs or entering data electronically on e-CRFs

- Monitoring the patient's safety and well-being throughout the study by recording any AEs, unanticipated adverse events (UAEs), or serious adverse events (SAEs)
- Dispensing, tracking, and storing any study medication or investigational medical device
- Accommodating the sponsor's monitoring visits

If the site does not utilize separate personnel to oversee the regulatory documents (e.g., institutional review board [IRB] submissions and approvals, continuing study renewals, UAE/SAE reporting, etc.), then the study coordinator will assume these responsibilities as well.

Another important role in clinical research is the clinical research associate (CRA), also known as the study monitor. The CRA is either employed by the sponsor or the sponsor-delegated contract research organization or is an employee of the academic institution. The CRA's primary duty is to conduct on-site visits, or *audits*, to ensure the research participants are eligible to participate in the study, are fully protected from harm, and are being treated with the utmost care.[1] The CRA also ensures the site is conducting the research study in compliance with the approved protocol, FDA Code of Federal Regulations, and IRB regulations by training the study personnel during the study start-up (site initiation) phase. They also reinforce protocol training and regulatory compliance throughout the study. While on-site, the CRA will examine all of the research participants' medical records as they pertain to the study and review the study CRFs (either paper or electronic) to ensure all data have been captured correctly. The CRA works closely with the study coordinator to correct any data errors and to resolve any data queries during and after the visit. The CRA usually meets with the PI and/or sub-I to review any issues that were uncovered during the visit. The CRA may visit a site as often as every 4 weeks, quarterly, or even annually depending on the type of study, length of study, and current study status. CRA visits can add a layer of work and may seem incredibly burdensome for the study coordinators. However, these visits are essential to ensure the study participants' safety and well-being, as well as the overall success of the study.

Written Consent

Once the research site has received IRB approval to begin the study, the site can begin screening and enrolling participants. The first step is always to obtain written informed consent from the patient prior to conducting any study-related procedures. Any designated study personnel can conduct the informed consent process with the potential participant; however, the person conducting the informed consent process must be adequately trained in how to conduct the process, as well as be knowledgeable in every aspect of the protocol. Per the ICH E6 Guidelines and FDA Code of Federal Regulations (21 CFR 50), the site is responsible for documenting the informed consent process in the participant's study file. The process entails: (1) allowing the research participant adequate time to read and review the informed consent; (2) discussing the study in detail with the participant; (3) allowing the participant to ask questions and answer any questions to their satisfaction; (4) witnessing the participant's signature/date by cosigning and dating the form; and (5) providing a copy of the informed consent form to the participant while filing the original version in the participant's study file. Additionally, most informed consent procedures include a separate informed consent form regarding the patient's rights that stem from the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The HIPAA section or separate consent form requires the patient to provide his or her signature of approval for the release of medical records and information for the study sponsor or any regulatory agency auditing the study.

Meeting Inclusion and/or Exclusion Criteria

Once the patients' informed consents have been obtained, the study coordinator can then begin to screen each potential study participant, performing the baseline visit procedures to determine whether the patient meets the inclusion/exclusion criteria for the study. The FDA Code of Federal Regulations and the ICH Guidelines explicitly warn against "prequalifying" a patient for a research study (refer to 21 CFR 50 and ICH E6 Guidelines). A site cannot perform any study-related procedures on a potential research candidate prior to obtaining that participant's informed consent. For instance, if the study requires certain lab results or an electrocardiogram (EKG) to be performed to determine eligibility, the research site cannot first draw STAT lab values or perform the EKG to determine whether the results comply with the inclusion criteria, and subsequently enroll the patient in the study. Therefore, the site must obtain the patient's full written consent before determining eligibility. However, some research protocols will allow potential study subjects to be prescreened or prequalified to determine study eligibility. In this case, a designated "prescreen informed consent form," completely separate from the informed consent form for the main portion of the study, is provided. This form must be approved by the IRB before being utilized with any potential patient. The prescreen informed consent form describes prescreening procedures the patient will encounter in detail, and this form clearly states that the patient will be undergoing prescreening for the study to determine eligibility. Whether prescreening or screening, an emphasis must be placed on obtaining the patient's consent in writing. Verbal consent is not allowed in a clinical research study and would be in direct violation of the federal regulations.

Baseline Visit

Baseline visit procedures to determine whether a patient is eligible to participate in a study can vary greatly. Baseline visit procedures typically consist of a medical history, physical exam, and routine lab work. Depending on the study, baseline visit procedures might also include other diagnostic tests, such as an MRI, echocardiogram, or pulmonary function test. The study coordinator may already have a good idea the patient will likely qualify to be enrolled in the study; however, he or she must wait until all of the procedures have been performed and the results obtained to determine eligibility. Once all of the data are available, the next step is to determine whether the patient has met the inclusion and exclusion criteria. To be eligible to participate in a research study, a patient must meet *all* of the inclusion criteria and *none* of the exclusion criteria. If the patient meets just *one* of the exclusion criteria, then the patient is excluded from participating in the study.

During a monitoring visit, the CRA ensures the study subjects were properly enrolled in the study by verifying whether each patient met the inclusion/exclusion criteria. The CRA performs a detailed audit of the study subjects' medical records, paying close attention to the baseline visit procedures that were performed to determine eligibility. If the patient meets all of the inclusion criteria and none of the exclusion criteria, then the patient is determined eligible to participate in the study and, therefore, can continue forward to the next phase. However, if the study's entrance criteria are not met, then the patient is considered a "screen failure" and is immediately withdrawn from further participation in the study. Properly determining study eligibility is as important as the informed consent process. The sponsor, IRB, and FDA always scrutinize these two processes to ensure health and safety. Research participants must be protected and well-informed of their study status at all times during a clinical study.

Randomization

After the eligibility phase, the next phase of a clinical research study is typically *randomization*. The randomization phase determines which study participants will receive the investigational drug or device and which participants will receive a placebo or control. Randomizing a study participant usually occurs in a 2:1 ratio—i.e., for every three subjects randomized, two subjects will receive the investigational medication, with one subject receiving a placebo or control. In this randomization scenario, a study subject has a greater than 50 percent chance of receiving the investigational medication. However, not all research studies involve a randomization phase. For instance, some medical device studies do not randomize the participants because the study plan is to have each participant receive some degree of exposure to the investigational medical device. In turn, these study subjects are often considered their own form of control (i.e., Did the device work for them or not?). With some research studies, the study design can become complicated regarding the randomization scheme. The sponsor or research institution may want all of the research participants to be exposed to the product being investigated at some point in the study. Therefore, randomization cross-over schemes are often included in the protocol. In this design study, subjects are randomized to either the placebo or active/investigational product group initially and then are crossed over to the opposite group after a certain period. From the study coordinator's perspective, ensuring the randomization has been performed correctly for each patient is another crucial step in the research process.

Follow-up

Following the randomization phase—or baseline visit if no randomization is planned—the research participants usually begin the follow-up visits for the study. The follow-up visit procedures may appear very similar to the baseline visit procedures. The same lab work, x-rays, EKGs, physical exams, and patient questionnaires may be repeated to some extent during these follow-up visits. Once again, it is the study coordinator's job to ensure that all of the follow-up study visit procedures are being conducted. As the first person to receive and review these results, the study coordinator must also be vigilant about the study exam results and/or data generated from these visits. During the follow-up visits, any trends or discrepancies in the patients' results can be detected. For instance, if several of the research participants' lab results indicate that their liver enzymes are abnormally high and are becoming increasingly higher as the study progresses, then the study coordinator can alert the PI and sub-I(s) regarding this trend. Together, the research team can alert the sponsor or the research institution's medical advisor. Therefore, the study coordinator is the protective watchdog over the research participants' health and safety.

Adverse Events

The scenario mentioned in the previous section regarding abnormally increasing liver enzymes is an example of an AE. The amount and severity of AEs most often determine whether an investigational drug or device application will be submitted to the FDA for approval. Most pharmaceutical and medical device sponsors, as well as research institutions, require the capture, report, and documentation of AEs to some extent in their research studies. The approved study protocol describes the extent to which AEs will be documented for that particular study. The ICH E6 *Guideline for Good Clinical Practice* (and similarly Code of Federal Regulations 21 CFR 310.305) defines an AE as follows:

> *. . . any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product, and that does not necessarily have a causal relationship with this treatment. An AE can, therefore, be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.*

For example, if a patient returns for the 3-month follow-up visit and reports to the study coordinator that they have had the flu for the past four days, this experience is considered an AE. Another type of AE that can occur in a research study is known as a serious adverse event (SAE). The ICH E6 *Guideline for Good Clinical Practice* (and similarly Code of Federal Regulations 21 CFR 312.32) defines an SAE as follows:

> *. . . any untoward medical occurrence that at any dose:*
>
> - *Results in death*
> - *Is life-threatening*
> - *Requires inpatient hospitalization or prolongation of existing hospitalization*
> - *Results in persistent or significant disability /incapacity*
> - *Produces a congenital anomaly/birth defect.*

Serious AEs must be reported immediately to the sponsor or research institution responsible for the study. The research site must report the SAE as soon as it becomes aware of the event, no longer than 24 hours from the time the event was initially registered. The sponsor or academic research institution will request that the research team obtain all available information surrounding the event (e.g., hospital records from admission to discharge or the death certificate). The process of collecting, documenting, and reporting AEs and SAEs is much more involved than this chapter covers. In order to assist the research community with AE reporting, the World Health Organization (WHO) created several guidelines and/or documents to help the research community better understand the importance of subject safety throughout the subject's participation in a research study, as well as navigate the various reporting requirements to each governing body in research. Generally, the sponsor reviews the data collection and reporting requirements in depth with the research site personnel during study start-up.[2]

Study Termination

The final phase of a research study is study completion or study termination. Research participants who have completed all of the required follow-up visits are then dismissed from the study. The procedures for the exit visit can be as extensive as those for the baseline visit. The research team wants to obtain as much data as possible during this visit, knowing that this visit is the last opportunity to collect any additional lab work, EKGs, x-rays, and/or patient questionnaires. Research subjects who have completed the study are rarely asked to come back and complete additional study visits to provide additional information. Study subjects can be withdrawn early or undergo early termination from a research study. The protocol usually provides guidelines and/or potential reasons for a patient's early termination or early withdrawal from the study. The most common reason is the patient no longer wishes to continue participating in the study and, therefore, voluntarily withdraws consent. Other reasons why a patient may be exited early from a study include the following:

- Patient is unwilling or unable to cooperate with study visits or procedures.
- Patient has experienced an AE or SAE.
- Patient relocates to a different area from where the research is being conducted.
- Patient is lost to follow-up (i.e., patient misses study visits, and the site is unable to contact the patient by phone, email, or certified mail).

IRBs most often want to know the reason(s) why a patient was withdrawn early from the study; therefore, they require the research team to document this information in the study records.

At first glance, the research team may feel that conducting a clinical research study appears to be rather easy. However, most clinicians have never participated in a clinical research project; therefore, they may be unaware of the significant amount of extra time and effort required. A study adds demands and responsibilities to the clinic's normal operations. On the other hand, participating in a clinical research project, or being asked to fulfill a specific role in one, can be a rewarding experience. Becoming involved in a clinical research project, as either a PI, sub-I, or study coordinator, allows practitioners to be on the cutting edge of a new drug, device, or procedure that could ultimately make a difference in the lives of many patients.

Phases of Clinical Research

Clinical research is most often performed to determine the safety and efficacy of a new drug or medical device and/or a new indication for either. Conducting clinical research on a new drug or medical device is extremely expensive. Most pharmaceutical and medical device sponsors spend millions of dollars attempting to receive approval for a single drug or device. The process of developing a new drug or device, conducting clinical research trials, and submitting an application to the FDA typically takes approximately 10 years, with most new drugs or devices never receiving FDA approval.

Clinical research trials involve four phases. Each phase is critical to the overall approval and success of a new drug or medical device. Furthermore, a clinical trial can be halted at any time and during any phase if too many adverse side effects or SAEs occur with the research participants.

Prior to phase I trials, preclinical studies may be conducted on animals to determine whether a new drug or device will be effective. Phase I clinical trials are the initial studies performed to determine the metabolism and pharmacokinetics of a drug (or a device) in humans. Phase I clinical trials are, therefore, considered "first-in-human" research studies. These studies are conducted on a small number of healthy participants (20–100) for a short time, usually for a few days to 1 month. Data regarding side effects associated with increasing doses and evidence of investigational product effectiveness are collected. Phase I studies are used to determine the maximum safe dose that can be tolerated and establishes toxicity.

Once the maximum safe dosage of an investigational product has been determined, the next step in the research trial process is to conduct a phase II clinical trial. A phase II clinical trial is a randomized, controlled study conducted to evaluate the effectiveness and therapeutic range of a drug (or a device) for a particular indication in patients with the disease or condition, as well as to determine common side effects and risks. Phase II research studies are longer than phase I studies, typically lasting a few months to 1 year. During phase II, study participants are randomized to receive either the investigational product or a placebo. Phase II studies involve a larger number of research participants (100–300).

After conducting phase II studies, sponsors have an established idea of the therapeutic range of the investigational product as well as the expected side effects. Sponsors then conduct phase III clinical trials to introduce the investigational product to a large number of participants (1,000–3,000). Phase III studies are extensive clinical trials usually conducted nationally (and even internationally) across multiple research sites. Phase III studies are usually randomized, controlled trials comparing the investigational product to placebo. These trials can be "open label" as well, with the research participants and research team aware of who is receiving the investigational product and who is not. Phase III trials are conducted to gather additional information on the overall benefits and/or risks of the product or device being investigated; they also provide a basis for product labeling. Sponsors prepare to submit their new drug or device application to the FDA for approval at the conclusion of the phase III trials. If the sponsor receives FDA approval for the new drug or device, then a phase IV clinical trial can be conducted.

Phase IV trials are "postmarketing" trials that can be either voluntarily conducted by the investigator or mandated by the FDA as a stipulation for the new drug or device approval. Either way, phase IV clinical trials are conducted to obtain a greater amount of safety and efficacy data in thousands of individuals (i.e., even more than phase II or III). During phase IV studies, the new drug or device is available to the public. Phase IV studies can provide additional information regarding risks, benefits, and optimal use that perhaps did not appear during the phase III studies. Because a large number of participants and data, the FDA recommends that more company-sponsored research involves phase IV clinical trials.

Summary

The overall goal of clinical research is to translate laboratory research into applied clinical interventions safely. The process must be transparent and follow the established national and international guidelines for conducting research on human subjects. It is, therefore, important that all parties understand the purpose and process of the investigation. Each of the steps from IRB protocol approval to the exit visit helps to maintain the integrity of the study and ultimately the results.

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SECTION 3

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CHAPTER 11

Data Analysis

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J. Glenn Forister, PhD, PA-C

CHAPTER OVERVIEW

This chapter provides a basic overview of the conventional statistical techniques used in quantitative studies. This concept related to these techniques should reinforce or advance the reader's understanding of statistics. A large number of books are available on statistics and statistical analysis, and every researcher should have at least one statistical analysis book as a reference. Decisions about data analysis must be made before data collection; data analysis planning is part of research methodology. Even those with a moderate understanding of statistics will benefit from consulting a statistician about the research design and analysis. Careful attention should be given to the type of research being conducted and the type of data produced by the investigation. Selection of the correct statistical tests results in proper data analysis and greater confidence in the conclusions drawn from the study's results. As a practicing healthcare professional, understanding data analysis is a vital part of interpreting medical and research literature.

LEARNING OBJECTIVES

- Define and describe the levels of measurement.
- Define descriptive statistics.
- Define inferential statistics.
- Describe the process of choosing a statistical test.
- Apply standard statistical tests to practice data.

Introduction

Why should clinicians use statistics? Although some healthcare providers earn advanced degrees and engage in health-related research, most are practicing clinicians. Most healthcare providers have been exposed to statistical analysis in their education; however, many view statistics as irrelevant to their clinical practice. The primary reason for clinicians to use statistics is to help them understand research articles that help to formulate decisions for their patients and practice. Healthcare providers decide daily on the most cost-efficient, least harmful, and most appropriate treatment plan. These decisions are best supported by the medical literature. Frequently, this effort requires some knowledge and appreciation of statistical analysis and inference.

Healthcare providers are not expected to be statisticians. Biostatisticians serve as consultants when clinicians conduct research studies.

Regardless of whether a healthcare practitioner ever participates in clinical research, critically analyzing the results of research studies to make clinical decisions is an integral part of healthcare practice. The following are the primary objectives in evaluating the data analysis of a research study:

- Become familiar with the types of data produced in the study
- Become familiar with the most common statistics used in medical journals
- Grasp how the study's conclusions flow from the results and statistical analyses
- Understand the rationale behind the selection of statistical analyses and how well specific analyses test the study's hypotheses

In this chapter, we explore descriptive statistics and inferential statistics, as well as the styles of results presentation, statistical reference texts, and computer software options. Mathematical and statistical formulas are used sparingly in this chapter.

Levels of Measurement

The first step in deciding on the appropriate type of statistical analysis is to determine the level of measurement to be used based on the type of data. The data types are shown in **TABLE 11.1**.

TABLE 11.1 Definitions of Data Types

Data Type	Definition	Example
Nominal data	Data that categorizes	Gender, eye color, race, graduating cohort, practice specialty
Ordinal data	Data defined by order, but the distance between the choices or values is not defined	Likert scales, preference scales, rankings
Interval data	Data with a defined interval between the values, but with no true zero value	Ambient temperature: Zero does not indicate a total lack of temperature; it is a value on a scale. The temperature interval difference between 61°F and 62°F is the same as the interval difference between –61°F and –62°F.
Ratio data	Data with an absolute zero value, where zero means there is a total absence of what is being measured	Visual acuity, range of motion, height, weight, blood pressure, blood alcohol level

As a general rule of thumb, the higher the level of measurement, the more information can be ascertained from the data. The most basic level of measurement is the nominal level, in which responses are divided into named groups or categories. For example, subjects might be asked to choose the group to which they identify: male, female, or non-binary. The subjects' choices allow the researcher to group individuals by category.

The nominal level of measurement limits the researcher in the type and number of statistical and mathematical analyses. Only descriptive or summary methods can be used. These data enable the researcher to determine how many subjects fall into each category. For example, in a survey of 100 healthcare professionals, 39 percent were male, 60 percent were female, and 1 percent were non-binary. Some common nominal data types are gender, race, religion, blood type, year in school, and home state. Consider nominal data as information that helps to categorize something or someone. In this case, nominal data is used for the basic description of individual characteristics. It should not be confused with more descriptive qualitative data exploring the lived experience of subjects, social phenomena or, discursive themes.

Ordinal measurement provides an ordering (sometimes ranking) between variables; however, the distance between each variable is not defined. For example, research subjects may be asked to indicate their degree of agreement or disagreement with a series of statements. There is no defined distance between "Agree" and "Strongly Agree" or between "Neutral" and "Disagree." One of the most common forms of ordinal measurement is the Likert scale. The traditional use of the Likert scale is to provide the subject with a statement and ask for the level of agreement or disagreement with that statement. The original Likert scale is a five-point scale with the following terms:

Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree

Although the scale offers more possibilities for an in-depth analysis than nominal measurement, ordinal measurement has limitations with regard to statistical analysis. Several types of ordinal scales exist, but each suffers from the lack of uniform distance between units for each respondent. The researcher cannot measure differences with the same amount of precision as interval or ratio data. Many ordinal scales are referred to as verbal frequency scales. These scales use wording such as "always," "sometimes," and "never." Numbers are often used for the responses to ordinal measurements. In essence, vague language such as "sometimes" is assigned a numeric value. One respondent's valuation of "sometimes" may differ from the valuation of another respondent. Both responses, however, are converted to the same number by the researcher using the ordinal scale. Whether these numbers can be analyzed using statistical tests for ratio or interval data is debatable. A statistician can help determine the best method of analysis when utilizing ordinal measurements.

The most sophisticated statistical analyses involve two higher levels of measurement, ratio and interval. With both of these measurements, there is an ordering of the points, but the distance between each point on the scale is exactly the same. Ratio measurement differs from interval measurement, however, in that the ratio measurement has an absolute zero. For example, research participants might be asked for the specific number of years since graduating college. A year is a well-defined and understood time interval, with the difference between any consecutive points the same. That is, the difference between 4 years and 5 years is the same as between 65 years and 66 years. A meaningful zero value would exist; therefore, this measurement is a ratio.

One example of an interval scale is ambient temperature. There is a zero value, but the presence of a zero value does not mean total absence of the studied variable. For example, 0 degrees Fahrenheit (0°F) does not mean the total absence of heat because you can have negative temperatures. Therefore, zero, in this case, is just one value on the interval scale.

Ratio and interval measurements are considered continuous data. Continuous data provide researchers with the possibility of using inferential

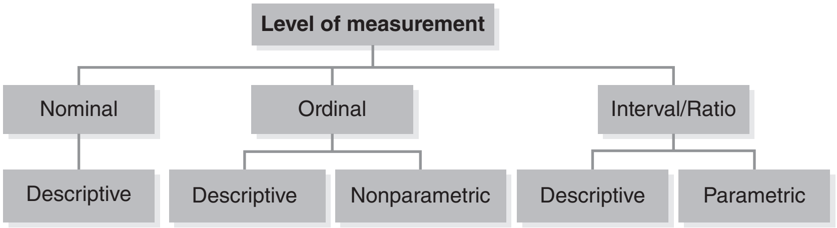

FIGURE 11.1 Levels of measurement.

statistics to determine the significance of differences and associations between groups and variables.

The four levels of measurement, as well as the appropriate types of statistical analyses to be used with each level, are illustrated in **FIGURE 11.1**. Keep in mind that the terms parametric (normal) and nonparametric describe the distribution of the subjects or variables.

Descriptive Statistics

A study may yield a significant amount of raw data that are organized and summarized by descriptive statistical methods. Summarizing the data is an essential first step in understanding the results. Then the researcher uses various inferential methods to help test the hypotheses of the study. Descriptive statistics are those processes or analyses that "describe" the sample. In many cases, this information is contained in the first table of the final published paper.

When summarizing data using descriptive methods, the fundamental concepts are *measures of central tendency* and *measures of variability.* Measures of central tendency are single scores used to represent a set of scores in a general way. The most commonly used measures are the *mean*, *median*, and *mode*. The mean is the sum of the scores divided by the total number of scores. The mean can be calculated for only interval or ratio variables. The median is the midpoint of a sequence of ordered variables or the point where half the values are above, and half are below. Medians can be calculated for ordinal, interval, or ratio variables. The mode is the most frequently occurring value. It can be determined for variables that are nominal, ordinal, interval, or ratio.

To illustrate the measures of central tendency, consider the following hypothetical data set: The lengths of stay in the cardiac care unit for seven patients following acute myocardial infarction were 3, 12, 5, 7, 5, 8, and 9 days. When performing the statistical calculation for this data set, the data are sorted first from the lowest to the highest numerical value: 3, 5, 5, 7, 8, 9, 12.

The mode (most frequently occurring score) is 5.
The median (the midpoint of the ordered scores) is 7.
The mean (sum of the scores divided by the total number of scores) is $3 + 5 + 5 + 7 + 8 + 9 + 12 = 49/7 = 7$.

By itself, measures of central tendency can give a misleading view of the data. For example, suppose that the lengths of stay for the second group of five patients were 7, 7, 7, 7, and 7 days, respectively. Similar to the first data set, the mean of this data set is 7. What differs, however, is the variability of the data. In the first group, the length of stay varies from 3 to 12 days. In the second group, everyone had the same length of stay: 7 days.

The three measures of variability most commonly reported in biomedical research are the *range*, *standard deviation*, and *standard error* of the mean. The range, which is the most straightforward measure, is the difference between the highest and the lowest scores. In the first example, the range is $12 - 3 = 9$. The range provides an easy "rough cut" of the variability, yet it is of limited value because it does not include all of the data in the computation. As a point of interest, the range of the second example is zero ($7 - 7 = 0$); this outcome is a statistical anomaly.

The standard deviation (SD) is the key descriptive statistic used to report variability. Mathematically, it is the square root of the variance. The variance is the sum of the squared differences between each score and the mean, divided by the number of scores minus 1. The formula for SD is

$$S = \sqrt{\frac{\sum (x - \bar{x})^2}{n - 1}}$$

where x = each score, $\bar{x}$ = the mean, and n = the total number of scores in the sample.

To determine the SD for the first example data set provided, the square root is calculated using the following equation:

$$[(3 - 7)^2 + (5 - 7)^2 + (5 - 7)^2 + (7 - 7)^2 + (8 - 7)^2 + (9 - 7)^2 + (12 - 7)^2]/(7 - 1)$$

This result is the square root of 9, or 3. The SD for this sample data set, therefore, is 3 days. The SD is the most commonly reported measure of variability.

The standard error of the mean (SEM) is another descriptive statistic. The SEM is the SD divided by the square root of n, and it represents an estimate of the population SD. In the previous example, the SEM is 1.1 (calculated by dividing 3 by the square root of 7).

Although the computation of such basic statistics can be performed with a statistical calculator, using computer software such as Microsoft Excel, SAS, or SPSS is preferred. Statistical software facilitates data management and computation.

Distributions, Normality, and Variance Equality

Although the measure of central tendency summarizes a collection of individual scores for a particular variable, the *distribution* includes the total set of scores. It helps to visualize the distribution of the data as one of the first steps in an analysis. Graphing the frequency of each score in a histogram with an overlapping line curve is one method.

Distributions have many differing shapes. **FIGURE 11.2** displays different examples of distributions.

A distribution's shape can be described as normal (symmetrical Bell curve), skewed (positively or negatively), bimodal (two modes), platykurtic (flat), and so forth. As a reminder, when the one tail of a distribution is longer than the other, the distribution is "skewed" in that direction. When the right tail is longer than the

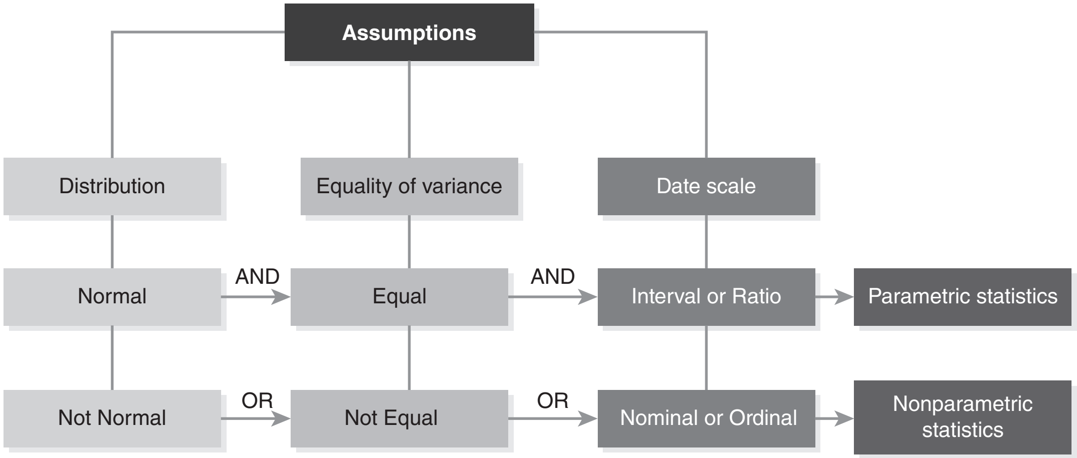

FIGURE 11.2 This figure shows some common shapes of sampling distributions. Note the differences in the location of the peaks and tails for each type.

left tail, the skew is positive. When the left tail is longer than the right tail, the skew is negative.

In addition to skewness, statisticians look at the kurtosis, the shape of the distribution's mound. When the mound of the distribution is flat, it is called "platykurtic," when peaked, it is called "leptokurtic," and when normal, it is called "mesokurtic." The Analysis ToolPak in Microsoft Excelgenerates summary statistics for each data column that includes measures of central tendency, variability, skewness, and kurtosis. A normal distribution will have a skewness value close to 0 and a kurtosis value close to 0 (or 3 depending on the statistical package). If the distribution of the population is normal, then according to the central limit theorem, the sampling distribution (a distribution of multiple samples from the population) will be normal. This explains why multiple sampling is considered more accurate than a single sample.

When comparing the scores in different distributions, the statistician will determine if there is equality of variance between the score groupings. If the distribution is normal and the score groupings are independent of each other, the F-test Two-Sample for Variances can be performed in using the Analysis ToolPak in Microsoft Excel. Typically, the *p*-value for this test will be >.05 if the variances are equal. If more than two groups are compared, the Levene's test for homogeneity of the variances can be performed using common statistical software programs. The *p*-value for Levene's test will be >.05 when the variances are homogeneous.

Inferential Statistics

Following a descriptive review of the data and determining the level of measurement, the researcher again asks the original question: What is the hypothesis? Most research studies are looking for either a relationship between two or more variables or a difference between the variables. In the study described here, we might be interested in determining whether there is a relationship between a patient's age and the days they spent in the hospital following a heart attack. In this case, we would probably perform a correlation analysis to determine the potential relationship between these variables. Conversely, if we had hypothesized that the length of stay in the hospital cardiac care unit was shorter for patients who had governmental insurance compared to patients with private insurance, we would analyze the differences between the groups. The length of stay in days would be the variable analyzed.

Inferential statistics are used to draw inferences about the results, mainly to test the hypotheses of a study. A researcher studying a problem usually formulates a hypothesis, such as "Aspirin reduces the incidence of colon cancer" or "Problem-based learning produces better clinicians than conventional instruction." Statistical inference, however, is based on testing a null hypothesis. The null forms for the hypotheses given here are "Aspirin has no effect on the incidence of colon cancer" and "There is no difference in the effectiveness of clinicians trained/educated by problem-based learning versus conventional instruction." Therefore, the researcher needs to consider how problem(s) is/are stated as the study develops.

In statistical hypothesis testing, the researcher and statistician select a significance level, called alpha (α). By convention, the α level is set at .05 or .01 and is reported without a zero in front of the decimal point ($\alpha < .05$). Remember, the α level is set by the investigator and can be some level other than the one indicated. However, selecting a value > .05 should be done with good reason. When the data are analyzed, the statistical test yields a *p*-value, the probability that the observed result could occur by chance if the null hypothesis is true. (The *p*-value is also reported without a zero in front of the decimal point.) If $p < \alpha$, then the researcher rejects the null hypothesis. If $p > \alpha$, then the researcher fails to reject (retains) the null hypothesis. If the researcher rejects the null hypothesis, then the researcher is saying that the opposite of the null hypothesis is true. If the researcher retains the null hypothesis, then the researcher is stating that the null hypothesis is true.

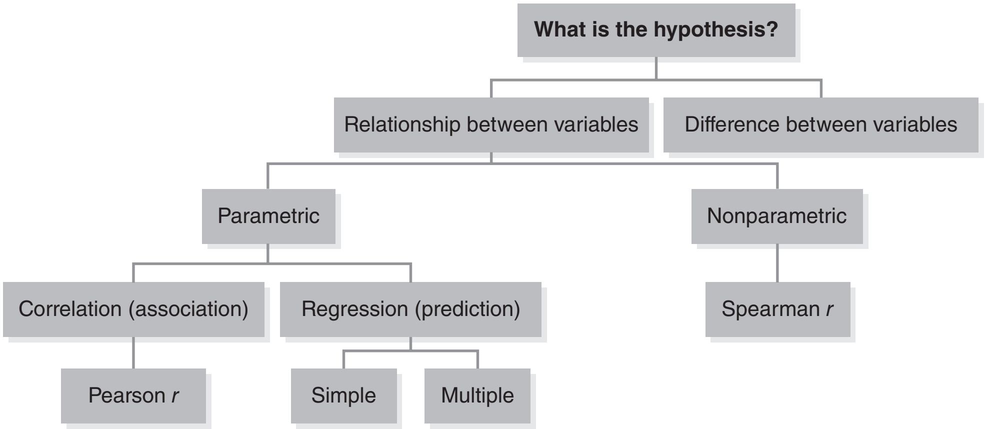
What is the hypothesis?
Relationship between variables
Difference between variables
Parametric
Nonparametric
Correlation (association)
Regression (prediction)
Spearman *r*
Pearson *r*
Simple
Multiple

FIGURE 11.3 Selecting statistical tests based on the hypothesis.

Selecting which statistical tests to use is a big question. There are hundreds of tests. Decision trees are provided in **FIGURES 11.3** and **11.4** as a reference guide for choosing some of the more common based on data type and study purpose. Descriptive statistics can be calculated and reported for each of the different data types. However, investigators want to go beyond mere description of the data to make inferences. To choose the correct inferential statistical procedure, one must attend to some basic underlying assumptions related to the data. To use parametric statistical procedures, the data

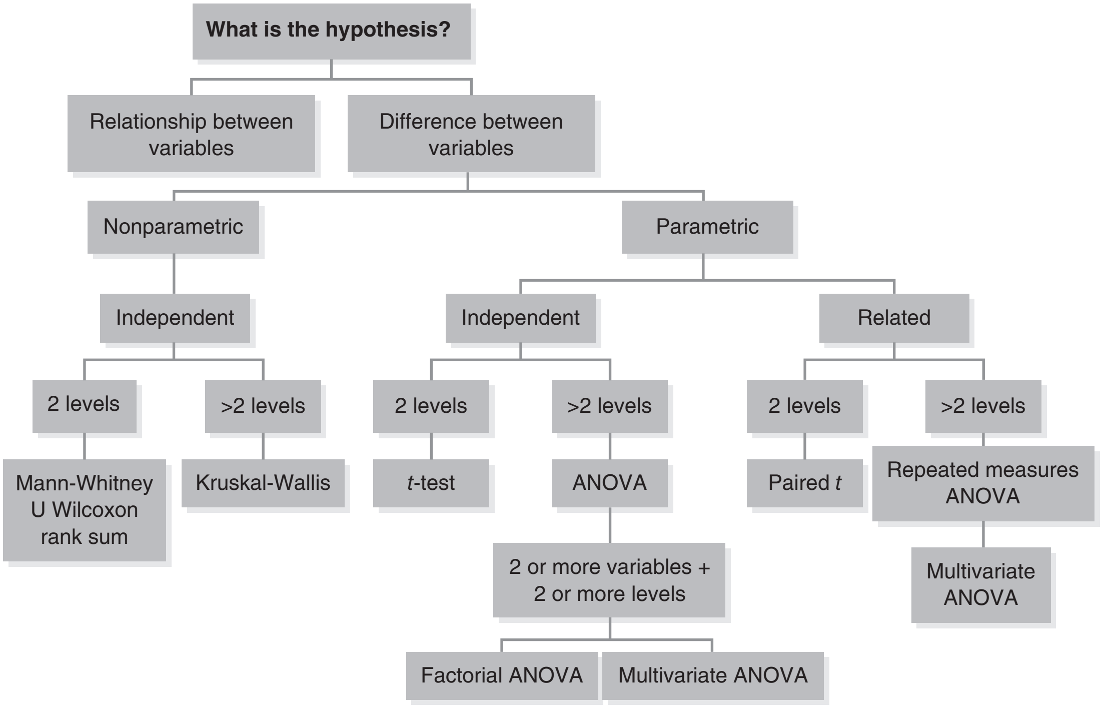
What is the hypothesis?
Relationship between variables
Difference between variables
Nonparametric
Parametric
Independent
Independent
Related
2 levels
>2 levels
2 levels
>2 levels
2 levels
>2 levels
Mann-Whitney U Wilcoxon rank sum
Kruskal-Wallis
t-test
ANOVA
Paired *t*
Repeated measures ANOVA
2 or more variables + 2 or more levels
Multivariate ANOVA
Factorial ANOVA
Multivariate ANOVA

FIGURE 11.4 How to select the correct statistical procedure.

must be normally distributed, with equal variance for the different groups of data, and the scale must be interval or ratio. If any of these assumptions are violated, then it is best to choose nonparametric statistical procedures.

Hypothesis Testing: Nominal Data

Many medical outcomes are measured on a nominal scale. For instance, one patient has a diagnosis of breast cancer; another patient has a second myocardial infarction. Epidemiological studies also yield nominal data—a patient did or did not get the disease. In a study about smoking, the null hypothesis might state, "Smokers are not more likely to have asthma." For this study, with smoking or not smoking as the variables, an appropriate statistical test would be the chi-squared (χ^2) test. (We realize that asthma is a multifactorial disease.) The χ^2 test is simply a way to determine whether an event has occurred more frequently than it would be expected to occur by chance. The observed χ^2 value is compared to the probability of an event occurring by chance. This is done using a χ^2 distribution table. For example, the observed value and degrees of freedom will correspond to a *p*-value on the table. If this value is <.05, the researcher can reject the null hypothesis, concluding there is sufficient evidence that asthma occurs more commonly in individuals who have a smoking history.

Epidemiological studies use nominal data to produce incidence and prevalence rates. For example, a study is conducted finding that cigarette smokers are seven times as likely to develop lung cancer or heart disease as those who never smoked. In other words, the relative risk for smokers is 7. Is this risk statistically significant? In this example, a confidence interval is used to test the null hypothesis, which indicates the relative risk = 1 (no added risk of smoking). If the researchers set $\alpha = .05$, then they use a confidence interval of 95 percent. Confidence intervals are reported as percentages. In this case, the confidence interval is found by calculating $[(1 - .05) \times 100\%]$ to give 95 percent. The 95 percent confidence interval for this example is 3.5. This means that the researcher can be 95 percent confident that the actual relative risk is between 3.5 and 10.5 (7 ± 3.5). Because the 95 percent confidence interval does not include the relative risk value of 1, the result is significant at the .05 level. Therefore, the researcher rejects the null hypothesis and concludes that smoking increases the risk of lung cancer or heart disease.

Analysis of Continuous Data: Measures of Association

Determining the association or relationship between two continuous variables (interval or ratio) is a common statistical problem. For instance, what is the relationship between a woman's age and hemoglobin level? What is the relationship between blood sugar level and weight in those who are obese? The measures of association most commonly used are subsumed under the general labels of correlation and regression.

Suppose a clinical educator is concerned about the reliability of an examination on interpreting electrocardiogram (ECG) tracings. Ten students are given a test on Monday and a parallel test on Tuesday. The exam scores are then correlated. Because the student scores are an interval/ratio variable, the Pearson product moment correlation technique can be used. The result of the statistical manipulation is an *r* value. This is the correlation coefficient. There are a few different formulas that can be used to calculate the correlation coefficient (*r*) manually; however, the value is typically generated using statistical software. Values of the correlation coefficient (*r*) vary between −1 (a perfect negative correlation) and +1 (a perfect positive correlation). An *r* value of zero indicates a lack of relationship. The scores on the 2 test days are graphed in **FIGURE 11.5**.

An experienced researcher/statistician would view Figure 11.4 and interpret the correlation as moderate to strong (based on the clustering of the points about a straight line) and as positive (i.e., as Monday's test scores increase, so do Tuesday's). The correlation in this example is

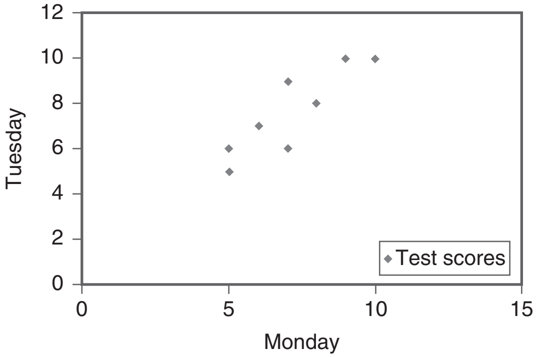

FIGURE 11.5 Test scores.

computed as $r = .88$. Is the result statistically significant? The null hypothesis of no relationship between the two tests' results (the variable), or $r = 0$, is tested at the .05 level of significance. The observed *p*-value is < .05. The researcher rejects the null hypothesis if there is no relationship and concludes there is a significant correlation between the two administrations of the ECG examination, supporting its overall reliability.

Multivariate regression techniques in which relationships among many variables can be examined simultaneously go beyond the simple two-variable correlation. Regression is based on the concept of predicting one variable from another and assigning a probability to these predictions. Complex multisite clinical trials and epidemiological studies are conducted utilizing these methods, including discriminant function analysis, factor analysis, path analysis, and logistic regression. Also, nonparametric correlation techniques exist for ordinal and ranked data. Discussion of these methods, however, is beyond the scope of this text.

Analysis of Interval/Ratio Data: Comparisons of Groups

The most powerful statistical tests are those that use interval and ratio data from well-designed studies. Ordinal data are often treated as if they are interval data and then are subjected to such tests. The decision as to whether this is acceptable should be left to the statistician. Even if an ordinal value is assigned a number value, the distance between the ordinal values is not defined. A technique known as Rausch analysis can be used with ordinal data, but it is again beyond the scope of this basic introduction.

An example of an appropriate use for analyzing the difference between groups is a research study involving a new antihypertensive drug tested against a placebo. Fifty patients are randomized to either treatment or control. After a course of treatment, the diastolic blood pressure is measured. The appropriate statistic to test the null hypothesis is the *t*-test (sometimes referred to as the student *t*-test). The researchers set the α level at .05. The statistical analysis produces a *t* value; in this case, $t = 6.4$. Using *t* tables yields a *p*-value <.05, so the researcher rejects the null hypothesis and concludes that the new drug significantly reduces diastolic blood pressure.

The *t*-test (or student *t*-test) is perhaps the most commonly used parametric test. It allows for a comparison of the means of two groups. (A paired *t*-test allows for comparison of the same group at two different times.) The *t*-test is a special case of a general set of methods collectively known as analysis of variance (ANOVA). Data from complex designs can be analyzed with ANOVA because multiple independent variables, multiple dependent variables, and many subgroups can be tested within a single ANOVA model.

The following example illustrates how to use only one independent variable and one dependent variable. Imagine that a study aims to test the efficacy of over-the-counter pain remedies for nonmigraine headache pain. A total of 25 patients are randomly assigned to one of five drugs in a double-blind manner. The patients are asked to rate their headache pain on a 0–10 scale (where 0 is no pain and 10 is excruciating pain). The null hypothesis is "There is no difference in pain ratings between pain medications." The α level is .05. After 1 month, the results are compiled and summarized. The researcher then performs an ANOVA test that produces an *F* ratio. The *F* value is reported with its associated degrees of freedom that are based on the number of comparison groups and the number of subjects. If the *F* yields a score that has a *p*-value <.05, then the researcher rejects the null hypothesis that there are no significant differences among the drugs. However, which drugs are different from the others? Several multiple comparison procedures are available. A biostatistician can assist in selecting the most appropriate test for the analysis. (*F* values are found in tables produced with most statistical texts, or generated by statistical software.)

Meta-Analysis

Many evidence-based medical studies and literature reviews rely on meta-analysis to simultaneously analyze a large number of research studies and determine a conclusion. Meta-analysis can be defined as a process of using statistical integration of the results of several studies to reach an independent conclusion. Meta-analysis is not a singular statistical test or procedure but rather a generalized conceptual approach. The steps to completing a meta-analysis are as follows:

1. Define the hypothesis.
2. Collect the *units of measurement*, that is, the research studies that have been done on the defined topic.
3. Convert the statistics to common values (e.g., *z* scores, *r* values, etc.).
4. Compute the measures of central tendency, variability, and prediction from the accumulated data measures.
5. Determine whether the hypothesis is supported.

Meta-analysis has several advantages. It is precise, rigorous, and quantifies decision making about a question. It is also more objective than traditional literature reviews. In a meta-analysis, the inclusion criteria account for the incorporation of multiple related studies, thereby limiting any biases. Additionally, a meta-analysis is replicable, at least in theory. Any reviewer should be able to reach the same conclusion if the same criteria are applied to the same studies. However, disadvantages do exist when conducting a meta-analysis. Because a variety of studies combine different measures of the same variables and statistical techniques in different settings, information about individual differences in the various studies may become lost. Sample size effect may be an issue as well, mainly if some studies have large sample sizes and some have small sample sizes.

Choosing a Statistical Test

A general guideline for *some* statistical testing is detailed here. Choosing the right statistical procedures to test the results of data collection can be a significant challenge. Most researchers begin by asking the question: What statistics do I need to make sense of my results?

The statistical tests that are performed should be the most appropriate for the study objectives. **BOX 11.1** contains a list of research purposes along with some common procedures. Primarily, data are analyzed to summarize them, to identify relationships, and to identify significant differences while controlling confounding variables for all three of these purposes. The results of data analysis allow the researcher to extrapolate his or her findings to a population or group within a population. The choice of statistical tests should be optimal for the type of data to be analyzed and should meet the purposes of that analysis.

Step One

Before selecting statistical tests, the researcher must determine which type of data are being collected: continuous (internal/ratio), ordinal, or nominal. Investigations can involve all three or only one type of data. The choice of statistical analysis depends on the type of data collected and how the data are compared.

BOX 11.1 Uses for Common Statistical Procedures

To summarize data:	Descriptive statistics
To examine the frequency relationship of one variable to a theoretical distribution:	Chi-squared test for goodness of fit
To examine the frequency relationship of two variables to each other:	Chi-squared test for association
To examine the measured relationship between two variables:	
For ordinal data:	Spearman's rho test
For continuous data:	Pearson's correlation coefficient
To examine the measured relationship of multiple variables:	Multiple regression test
To examine the significance of difference between groups:	
For one group:	*t*-test
For two independent groups:	
Ordinal data:	Mann-Whitney test
Continuous data:	Independent samples *t*-test
For two related groups:	
Ordinal data:	Wilcoxon matched pairs test
Continuous data:	Paired samples *t*-test
For multiple independent groups:	
One independent variable:	One-way ANOVA
Multiple independent variables:	MANOVA
For multiple related groups:	Repeated measures ANOVA

Step Two

Once the type of data required has been determined, the researcher must decide whether the data are parametric or nonparametric.

- Parametric analyses assume a normal or near-normal distribution exists. For continuous data, a normal or near-normal distribution is always assumed.
- Nonparametric analyses do not assume a normal distribution exists. Nonparametric analyses can be done on data with a normal distribution, but they are not as powerful as parametric tests. Nonparametric tests are typically used for ordinal and nominal data. These tests can be used to analyze data from studies with small samples, especially when the results do not follow a normal distribution. Continuous data can be converted to nominal or ordinal form. An example would be grouping ages into age range bins.

Step Three

The researcher carefully considers the relationships of the data. Are the results paired or matched?

- Result data are considered paired if the same sample is measured after some intervention (e.g., a treatment of some type).
- Matched samples are those in which the characteristics of the experimental group are matched as closely as possible to a control group.

Step Four

The number and type of variables play a part in the choice of tests: one, two, or more than two (multiple), as well as independent or dependent. There may be no independent variables, one independent variable, or multiple independent variables. Statistical tests are for each dependent variable. There may be more than one dependent variable for each independent variable, but multiple measurements are for each dependent variable only.

Step Five

What is the researcher trying to explain?

1. The relationship between variables

OR

2. The difference between variables

Different tests are used to examine these relationships and differences.

Statistical Tests

The following statistical tests are the most commonly used tests in research. These descriptions are designed to provide a starting point and basic concept for the reader to develop an idea of what the tests are and when they should be used. Many more statistical tests are available, and the choice of tests depends on study design and types of data.

Descriptive statistics: The four trends of the sample are mean, mode, median, and range. They are used to describe the sample and sometimes to demonstrate how the sample may reflect a population if that population's measures of central tendencies (descriptive statistics) are known.

t-test: Tests the difference between two groups' means; can be one-tailed or two-tailed; can be used with paired or unpaired samples. Sometimes called the student *t*-test.

Analysis of variance (ANOVA): Tests the differences among the means of three or more groups for one or more variables.

Analysis of covariance (ANCOVA): A variant of ANOVA that allows adjusting for extraneous, additional, or undesired variables.

Multiple analysis of variance (MANOVA): A variant of ANOVA that allows for the study of multiple dependent variables. If MANOVA results are significant, ANOVA must be done for each variable.

Cochran's Q test: Compares proportions among three or more matched groups.

Duncan range test: A test used after ANOVA to identify means that differ significantly from one another.

Kendall's rank correlation: A test of the linear relationship between two ordinal or continuous variables.

Kruskal-Wallis test: A nonparametric test for significance when using two independent samples. It is comparable to ANOVA, but for rank-ordered data.

Mann-Whitney test: Sometimes called the Mann-Whitney U-test, it is the nonparametric equivalent of a *t*-test. Used with ordinal data for two groups.

Multiple regression analysis: Any statistical method that evaluates the results of more than one independent variable on a single dependent variable.

Newman-Keuls test: Tests for significance in multiple post-hoc comparisons.

Pearson's χ^2 test: A test of categorical data for the goodness of fit or comparisons of observations.

Pearson's product moment test: A test of the strength of the linear relationship between two interval or ratio (continuous) variables.

Regression analysis: A method of predicting dependent variable variability by one or more independent variables. Most commonly used are simple linear regression and multiple linear regression.

Spearman's rho: A test that demonstrates the degree of relationship between two ordinal variables that may not have a normal distribution.

Tukey test: A test to identify significantly different groups after ANOVA.

Wilcoxon rank sum test: A test of significance for two paired, ordinal data samples.

Tests that can be used with continuous (ratio/ordinal) data:

- Descriptive statistics
- *t*-test
- ANOVA
- ANCOVA
- MANOVA
- Duncan range test
- Kendall's rank correlation
- Pearson's product moment test
- Regression analysis
- Multiple regression analysis
- Tukey test

Tests that can be used with ordinal data:

- Descriptive statistics
- Cochran's *Q* test
- Kendall's rank correlation
- Kruskal-Wallis test
- Mann-Whitney test
- Pearson's χ^2 test
- Spearman's rho
- Wilcoxon ranked sum test

Which Test to Use?

The choice of the right statistical test can add power to study findings and provide strong support for outcomes and conclusions. Because so many tests (many more than those listed here) are available, much confusion reigns in the realm of statistical analysis, especially for novice investigators. Many investigators use the tests that are most familiar to them, that is, tests they have used in the past. Understanding what a statistical test can and cannot do is very valuable, but using only one or a few familiar tests for all data analysis can create research limitations or lead to faulty conclusions.

The number of dependent and independent variables influences the choice of tests more than the category of the data (i.e., nominal, ordinal, continuous). Each *dependent variable* is tested separately, resulting in one big question for the researcher: What do I want to do: summarize, explore relationships, or test for significance of difference?

Summary

In this chapter, we presented the different scales of measurement used in biomedical and educational research. We reviewed differences between descriptive and inferential statistics, including hypothesis testing. Lastly, we introduced the factors related to the selection of statistical tests. Healthcare professionals participating in research projects need to understand the rationale behind the biostatistician's statistical analyses and how to test the study's hypotheses. The Recommended Resources section also provides the basis to perform selected data analyses.

Recommended Resources

- Creswell, JW, Creswell JD. *Research Design: Qualitative, Quantitative, and Mixed Methods Approaches.* 5th ed. Thousand Oaks, CA: Sage; 2018.
- Glantz, SA. *Primer of Biostatistics.* 7th ed. New York: McGraw-Hill; 2011.
- Glantz SA, Slinker BK, Neilands TB. *Primer of Applied Regression and Analysis of Variance.* 3rd ed. New York: McGraw-Hill; 2016.
- Harris M, Taylor G. *Medical and Health Science Statistics Made Easy.* 3rd ed. Banbury: Scion; 2014.
- Katz, DL, Elmore JG, Wild DM, Lucan SC. *Jekel's Epidemiology, Biostatistics, and Preventive Medicine.* 4th ed. Philadelphia, PA: Saunders Elsevier; 2013.
- Lang TA, Secic M. *How to Report Statistics in Medicine: Annotated Guidelines for Authors, Editors, and Resources.* 2nd ed. Philadelphia, PA: American College of Physicians; 2006.
- Norman GR, Streiner DL. *Biostatistics, The Bare Essentials.* 4th ed. Shelton, CT: People's Medical Publishing House; 2014.

Computer Software

Software for statistical analysis is categorized as (1) general purpose data analysis programs with statistical application, (2) complete statistical packages, and (3) special-purpose software for specific applications.

General Purpose Data Analysis Software

Microsoft Excel: Part of Microsoft Office; general purpose software includes several statistical tools. The Analysis ToolPak is an available add-on. In Excel, click on Options>Add-Ins>Analysis ToolPak>OK. Once installed, the Analysis Tool-Pak will be displayed in the data tab.

Complete Statistical Packages

SAS: SAS, Inc., Cary, NC. A comprehensive package biostatisticians frequently use for large projects. Website: http://www.sas.com

SPSS: SPSS, Inc., Chicago, IL. A comprehensive package frequently used by social science researchers, but also used by some biostatisticians. Website: http://www.spss.com

Stata: StataCorp, LP, College Station, TX. A comprehensive package with excellent graphing capabilities. Website: http://stata.com

Specialized Software

GraphPad Prism: GraphPad Software, Inc., La Jolla, CA. A program that includes free online quick calculators for various common statistical tests. Website: http://www.graphpad.com. Free calculators are available at http://www.graphpad.com/quickcalcs/

SigmaPlot: Systat Software, San Jose, CA. Primarily a graphing package, it includes extensive analysis tools. Website: http://www.sigmaplot.com

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CHAPTER 12

Exploring Statistics Comparing Differences in Health Care

J. Glenn Forister, PhD, PA-C

CHAPTER OVERVIEW

This chapter explores some of the frequently used statistical procedures including the interpretation of parametric tests assessing differences between groups. The statistics used to assess two or more related or independent groups on the basis of single or multiple variables are emphasized. The chapter is restricted to the various forms of the *t*-test and ANOVA because many randomized controlled trials and other clinical studies use these analyses. Although the multivariate versions of the *t*-test and ANOVA are typically excluded from introductory texts, an essential discussion of these procedures has been included. As healthcare researchers explore larger data sets with advanced statistical software, it is likely that readers will encounter such multivariate tests reported in the literature.

LEARNING OBJECTIVES

- Define *test statistic*.
- Describe commonly used statistics that compare groups.
- Compare the null hypothesis of the different forms of the *t*-test and ANOVA.
- Define *noninferior design*.
- Calculate and interpret an effect size.

Introduction

No single chapter can do justice to the topic of statistical interpretation. However, many articles in the healthcare literature are concerned with comparing the differences between two or more groups. Therefore, it is appropriate to discuss the commonly employed parametric procedures that examine differences, such as *t*-tests and the different forms of ANOVA. These statistical tests may be misunderstood or misinterpreted by health professionals.[1] The purpose of this chapter is to provide a basic understanding of how to assess differences *within* groups and differences *between* groups. Readers should note that other statistical techniques do appear in the healthcare literature; this chapter reviews parametric tests used in one out of three articles published in four of the top medical journals.[2] For some readers, this chapter will be a review; for others, it will be an introduction to some of the essential parametric statistics used to analyze group differences in health care.

Comparing Groups

Study participants are usually divided into groups. Frequently, the goal of medical research is to compare groups of patients in a meaningful way while controlling for random chance. Healthcare professionals need to answer three essential questions about the groups studied:

1. Did something different occur between the groups (usually due to some intervention or treatment)?
2. If something different occurred between the groups, was it due to chance?
3. If something nonrandom occurred between the groups, how large was the effect (was the difference clinically meaningful)?

These questions are answered, in part, by test statistics. The interpretive process may appear complicated initially but is always related to these three essential questions. The first two questions pertain to the null hypothesis. If something different occurred between the groups, the null hypothesis is rejected. If nothing different occurred between the groups, researchers would fail to reject the null hypothesis. The observed test statistic, such as the *t* statistic or the *F* ratio obtained from various computational procedures, is compared to the critical value on the corresponding distribution tables to help answer the first two questions. Assuming the population distribution is normal, and variances are equal, each of the test statistics has a known distribution when the null hypothesis is true. Readers should remember, however, that different *p* values result in different type I error rates. Statistical significance should never be confused with clinical significance. Statistical significance is about the likelihood of observing the results—nothing else. Although calculations for effect size can help answer question three, clinicians ultimately interpret the clinical meaningfulness of study results.

As a reminder, the groups can be unrelated to each other (independent) or related in some way (dependent). The most straightforward comparison occurs between two groups using one categorical independent variable and one continuous dependent variable. In this case, the preferred tests are the independent samples *t*-test (for independent groups) and the paired *t*-test (for dependent groups). When more than two groups are studied, the commonly used tests are the one-way ANOVA (for multiple independent groups) and the repeated measures ANOVA (for multiple related groups). Again, each of the tests examines differences between the groups using a single dependent (outcome) variable.

The complexity of test interpretation increases when (1) the groups are categorized using more than one independent variable, (2) the design is mixed (using both independent and repeated measures), or (3) multiple dependent variables are measured. When more than two groups are categorized using more than one independent variable, the one-way ANOVA is replaced by factorial ANOVA.

When multiple dependent variables are measured between two groups, the *t*-tests are replaced with a procedure called Hotelling's T^2. However, when multiple dependent variables are measured between more than two different groups, the proper procedure is multiple analyses of variance (MANOVA). If the multiple groups are related and measured on more than one dependent variable, a repeated measures MANOVA is used. Each of the tests mentioned thus far will be discussed in the following sections.

t-Test (Student *t*-Test)

The *t*-test assesses the difference between the means of two unrelated groups or independent samples. The null hypothesis is represented as H_0: $\mu_1 = \mu_2$ and is analogous to saying there is no difference between the group means. Most students remember this statistical test, but that is not the reason it is called the "student" *t*-test. The student *t*-test was given that name because Gossett, the Guinness Brewery's statistician who published the procedure, used the name "student" to remain anonymous.[3] The test is simply the ratio of the difference between two group means and the standard error of that difference. This ratio is often called the signal-to-noise ratio. This test is useful because it takes sample size into account. The obtained *t* statistic is calculated using the following formula (usually generated by software):

$$t = \frac{(\text{Mean G1} - \text{Mean G2})}{\sqrt{\frac{s^2_{G1}}{n_{G1}} + \frac{s^2_{G2}}{n_{G2}}}}$$

where

S^2_{G1} = variance of group 1

n_{G1} = number of subjects in group 1

S^2_{G2} = variance of group 2

n_{G2} = number of subjects in group 2

The obtained value of *t* is then compared to the critical value of *t* found in a table that defines the level of significance on the *t* distribution. Based on the directional nature of the hypothesized difference between the groups, the critical value is situated in a one-tailed or two-tailed position. If the researcher hypothesizes the results will occur in one direction, a one-tailed test is used. Usually, the researcher cannot be sure about the direction of the results. Therefore, a two-tailed test is more commonly used. The tails of the *t* distribution are represented in **FIGURE 12.1**.

Some researchers use a one-tailed test to establish noninferiority. The noninferior study design does not attempt to demonstrate a new therapy is better than standard therapy, only that it is *not substantially worse* than standard therapy. In this case, statistical significance is more likely to be achieved because the significance level (.05) is not divided into two directions. Moreover, the null hypothesis in a noninferior design is that the new treatment is worse than the standard therapy. Most health professionals are interested in new therapies that are superior to and more effective than standard therapy. Two-tailed tests are more conservative than one-tailed tests. For this reason, it is important to note whether the *t*-test reported in a clinical trial is one-tailed or two-tailed.

The null hypothesis is more likely to be rejected when (1) mean differences are large, (2) variances are small, and (3) sample sizes are large.[4] However, if the difference between the means is small and the variability within the groups is large, then a smaller number will be divided by a larger number, thus reducing the value of *t*. In such cases, researchers often fail to reject the null hypothesis, sometimes resulting in

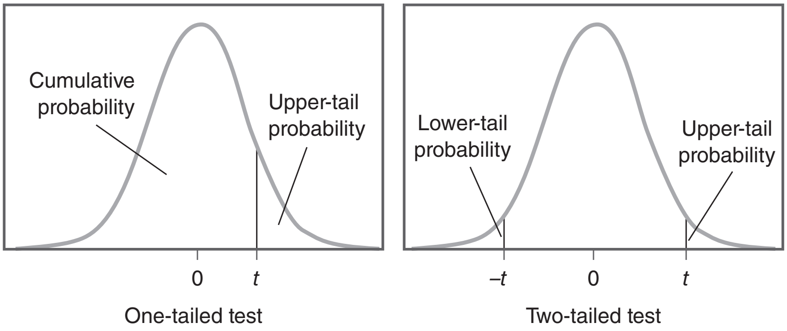


FIGURE 12.1 The *t* distribution.

a type II error. Furthermore, the power to detect a difference is influenced by the sample size. When using a *t*-test, each group should include a minimum of 15 individuals.[4] The researcher should report the *t* statistic, the associated *p*-value (level of significance), and the degrees of freedom (df). For example, when reporting an intervention group's score was better than the control group's score, the author provides the following: intervention mean, intervention standard deviation (SD), control mean, control SD, df, $t =$ calculated statistic, $p < .05$.

If something nonrandom occurred between the two groups, the next task is to determine if the difference is meaningful. One way to assess the magnitude of the difference is to calculate an effect size. The effect size calculation for the *t*-test is called Cohen's *d* (the treatment effect in standard deviation units). The general formula is:

$$\mathrm{d} = \frac{\mathrm{Mean}_{G1} - \mathrm{Mean}_{G2}}{\mathrm{SD}_{\mathrm{Pooled}}}$$

where

$$\mathrm{SD}_{\mathrm{Pooled}} = \sqrt{\frac{(\mathrm{SD}^2_{G1} + \mathrm{SD}^2_{G2})}{2}}$$

Accepted interpretation guidelines[5] for Cohen's *d* are presented in **TABLE 12.1**.

Example

Researchers conducted a study to determine if a group of 30 health professions students exposed to videotaped patient case studies exhibited higher exam scores than an independent group of 32 students exposed to standard lectures. The exam scores of the two groups were compared using the student *t*-test. The simulation group scored a mean (SD) of 82 (7.45), and the lecture group scored a mean (SD) of 80.5 (7.05). The mean of the simulation group minus the mean of the lecture group = 1.6, $t = .87$, df = 60, $p = .39$.

TABLE 12.1 Generally Accepted Guidelines for Cohen's *d*

Effect Size	*d*
Small	0.20
Medium	0.50
Large	0.80

Because of the small sample size, the 95 percent confidence interval of the difference between the groups ranges from –2.08 to 5.28, indicating the results could go either way when the study is repeated. The *p*-value exceeds .05; therefore, the researchers failed to reject the null hypothesis and concluded the videotaped case studies did not result in better exam performance than the standard lecture. No effect size is calculated when the groups' means are equivalent under the null.

Paired *t*-test (Matched *t*-test)

The paired *t*-test is considered more powerful than the independent samples *t*-test because less variability (noise) is created by the dependent nature of the samples.[4] Usually, two sets of data are collected from the same group of individuals. Often, some form of intervention occurs between the data collection activities. For example, the paired *t*-test is used in pretreatment–posttreatment study designs examining the same group of patients. The two sets of data in this experimental design may be referred to as two dependent groups. The terminology can be confusing because the word *groups* usually refers to individuals, not data sets; however, in a paired *t*-test one group of individuals serves as their controls. The same study participants are treated and assessed to see if the dependent variable changes. The data collected before the intervention can be considered a group and the data collected after the intervention can be considered a group. The null hypothesis is represented as $H_0: \mu_{\mathrm{before}} = \mu_{\mathrm{after}}$.

As in the student *t*-test, a ratio of signal-to-noise generates a *t* statistic. The formula for this ratio is:

$$t = \frac{d}{\sqrt{\dfrac{\sum d^2 - \dfrac{\sum d^2}{n}}{n(n-1)}}}$$

where
d = difference in paired sources
n = number of paired scores

The calculated value of *t* is compared to the critical value of *t*, and the researcher either rejects or fails to reject the null hypothesis. The results from paired *t*-tests will be reported in the same manner as for a *t*-test. Authors should provide the mean scores before and after the intervention along with standard deviations, the *t* statistic, and the *p*-value. If the null hypothesis is rejected, the effect size and clinical meaningfulness of the results should be assessed in the same manner as the student *t*-test.

Example

A single group of 44 patients with a first-degree medial collateral ligament tear of the knee were treated with a new cooling gel for pain relief. The investigators assessed the patients' pain scores using a validated numeric rating scale from 1 to 10. Before the gel application, the patients' mean (SD) pain score was 6.4 (1.3). Fifteen minutes after the gel application, the patient's mean (SD) pain score was 5.5 (1.7). The difference in the mean pain score was 0.9 with a 95 percent confidence interval of 0.26–1.54, $t = 2.79$, df $= 86$, $p = .006$.

In this example, the investigators can reject the null hypothesis and calculate a Cohen's *d* (0.59, medium effect size); however, clinicians reviewing the study will ultimately determine if the results are meaningful. For instance, some readers may question the use of ordinal data (the pain scale) in a parametric comparison. Parametric procedures are applied using interval or ratio scaled data. It is, however, common to see ordinal scales for pain and other measured outcomes in the healthcare literature. Readers must decide to accept or reject the results of such analyses. In this example, clinicians may decide to reject the analysis based on the use of ordinal data, or based on the fact that other forms of treatment are more useful than the gel because of greater pain relief achieved over a longer duration. Although the results of the paired *t*-test are statistically significant, readers may require additional evidence that the gel works. For example, the investigators may decide to measure the amount of pain medication used by patients over more than one-time interval by employing a repeated measures ANOVA—discussed later in this chapter.

One-Way ANOVA

The one-way ANOVA is an extension of the *t*-test involving more than two groups. This test assesses the relationship between a categorical independent variable and a single continuous dependent variable. The null hypothesis of ANOVA is represented as $H_0: \mu_1 = \mu_2 = \mu_3 \ldots = \mu k$ (where *k* indicates the number of groups). The *t*-tests discussed previously represent a signal-to-noise ratio, with the signal identifying the true difference between the groups and the noise separating the variability within the groups. In ANOVA, the signal-to-noise ratio is the *F* ratio (also called the *F* test). The *F* ratio includes the variance between groups (explained variance, or signal) and the variance within groups (error variance, or noise), therefore, *F* = variance between groups/variance within groups.

$$F = \frac{\text{MS Between}}{\text{MS Within}}$$

The total sums of squares (SST) results from adding the squares of all the deviation scores. In ANOVA, the total sums of squares is partitioned into sums of squares between (effects, SSB) and sums of squares within (error, SSW). The formula is SST = SSB + SSW. This procedure allows investigators to decide how much of the difference in scores is due to treatment and how much of the difference in scores is due to chance. The mean

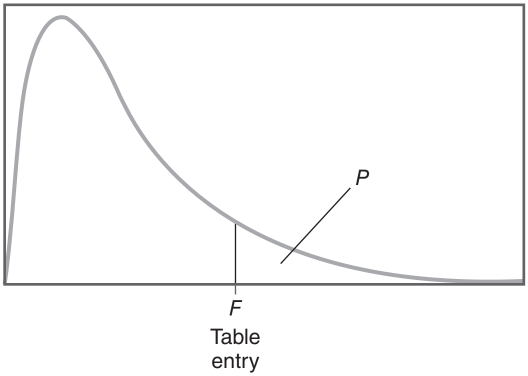


FIGURE 12.2 The *F* Distribution.

squares (MS) is found by dividing the sums of squares by the degrees of freedom (df). The researcher fails to reject the null hypothesis when the calculated value of *F* does not exceed the critical value of *F* (on the *F* distribution table). See **FIGURE 12.2**.

FIGURE 12.3 illustrates how the source table of a one-way ANOVA is constructed for three groups. Although the statistical software will perform the calculations and produce a source table (see **TABLE 12.2**), the following steps can be used to generate an *F* ratio manually:

Step 1: List the groups' raw scores separately in columns.

Step 2: Square each of the individual raw scores to produce another set of columns and sum each column, then produce quantity A by adding the totals.

Step 3: Find the total of all individual raw scores and square the total value, then divide the total by the number of individuals to produce quantity B.

Step 4: Calculate the SST by subtracting B from A.

Step 5: Sum each raw score column, square each sum, and divide each result by the number of individuals in the group.

Step 6: Sum the results from Step 5 to produce quantity C.

Step 7: Calculate the SSB by subtracting B from C.

Step 8: Calculate the SSW by subtracting SSB from SST.

Step 9: Divide SSB by the number of groups minus 1 to generate the mean squares between (MSB).

Step 10: Divide SSW by the number of individuals minus the number of groups to generate the mean squares within (MSW).

Step 11: Calculate the observed *F* ratio by dividing MSB by MSW. (Compare this value with the critical *F* on the *F* table.)

Some published studies using ANOVA will contain the source table; others will not.[3] Although the *F* ratio allows for hypothesis testing, the interpretation of ANOVA requires further comparisons. Assuming the null hypothesis is rejected, the investigator must determine how the groups differ from each other. The statistical software will generate comparisons—group one with group two, group one with group three, group two with group three, and so forth—with a series of post hoc (after the fact) tests. This process is analogous to *t*-testing but produces the problem of multiple comparisons. Because the likelihood of finding significance by random chance increases with the number of comparisons, the software will adjust the *p*-value (significance level), dividing it by the number of comparisons (called the Bonferroni correction).[4] The Bonferroni correction, however, can lead to an increased chance of type II error.[4] Therefore, other post hoc tests have been developed with names such as LSD, Tukey, Sidak, and Scheffé. The purpose of these tests is to reduce the chance of a type I error due to multiple comparisons.

Researchers should indicate which post hoc test was used after finding significance in an ANOVA. Once the difference is discovered, the final step is to establish its effect size. Healthcare professionals need to decide if the differences are clinically meaningful. To determine how much of the variance in the dependent variable is explained by the independent variable, a statistic known as eta-squared (η^2) can be calculated from the ANOVA table:

$$\text{eta}^2 = \frac{\text{SSB}}{\text{SST}}$$

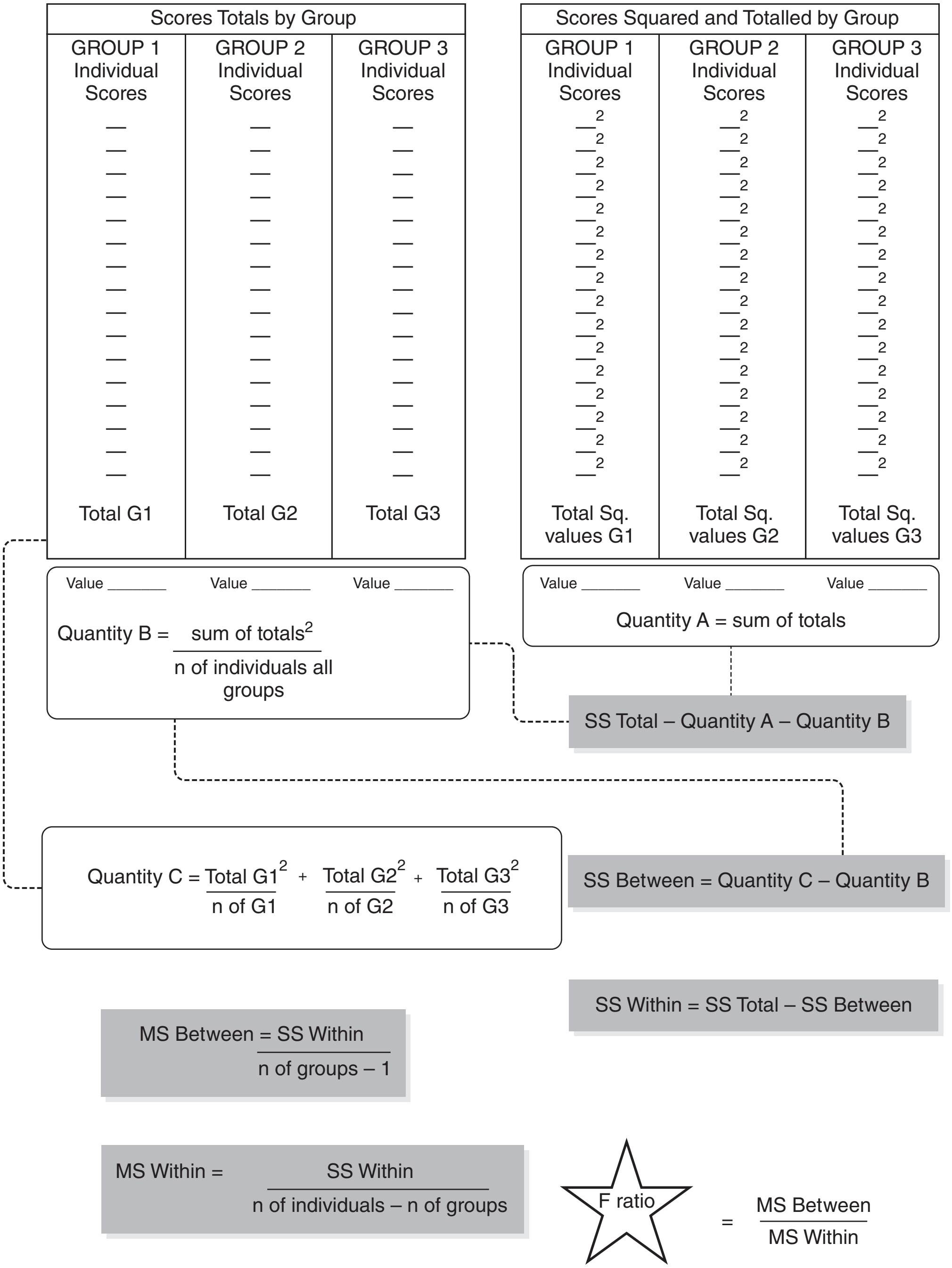

Scores Totals by Group
GROUP 1 Individual Scores
GROUP 2 Individual Scores
GROUP 3 Individual Scores
Total G1
Total G2
Total G3
Scores Squared and Totalled by Group
GROUP 1 Individual Scores
GROUP 2 Individual Scores
GROUP 3 Individual Scores
Total Sq. values G1
Total Sq. values G2
Total Sq. values G3
Value _______
Value _______
Value _______
Quantity B = sum of totals² / n of individuals all groups
Value _______
Value _______
Value _______
Quantity A = sum of totals
SS Total – Quantity A – Quantity B
Quantity C = Total G1² / n of G1 + Total G2² / n of G2 + Total G3² / n of G3
SS Between = Quantity C – Quantity B
SS Within = SS Total – SS Between
MS Between = SS Within / n of groups – 1
MS Within = SS Within / n of individuals – n of groups
F ratio
= MS Between / MS Within

FIGURE 12.3 One-Way ANOVA.

TABLE 12.2 The F Value and Associated P Value from the ANOVA Source Table Allow for the Interpretation of Between Group Statistical Significance and Hypothesis Testing

Source	Sum of Squares	df	Mean Squares	*F*	*p*
Between groups	SSB	Number of groups minus 1	MSB	MSB/MSW	<.05 from the *F* table
Within groups	SSW = SST – SSB	Number of individuals minus number of groups	MSW		
Total	SST				

Some investigators may report effect size using omega-squared (ω^2). The formula for omega-squared is:

$$\text{omega}^2 = \frac{\text{SSB} - [(\text{k} - 1)(\text{MSW})]}{\text{SST} + \text{MSW}}$$

TABLE 12.3 includes the effect size interpretation guidelines[4] for values of η^2 and ω^2.

Example

Many researchers include a graphical representation of group outcomes related to each other. For example, **FIGURE 12.4** shows how three different treatments for diabetes affect mean hemoglobin A1C levels. The treatments in this example are (1) usual care, (2) exercise, or (3) dietary counseling. “The *p*-value for the comparison between Group 1 (usual care) and Group 2 (exercise) or Group 3 (diet) was less than 0.05, and the null hypothesis of no difference can be rejected for Group 1 versus Group 2, or Group 3. However, the *p*-value for the comparison of Group 2 to Group 3 was greater than 0.05, so the null hypothesis of no difference

TABLE 12.3 Interpretation Guidance for Effect Size Calculations

Effect Size	Eta² (η^2)	Omega² (ω^2)
Small	0.01	0.01
Medium	0.06	0.06
Large	0.14	0.15

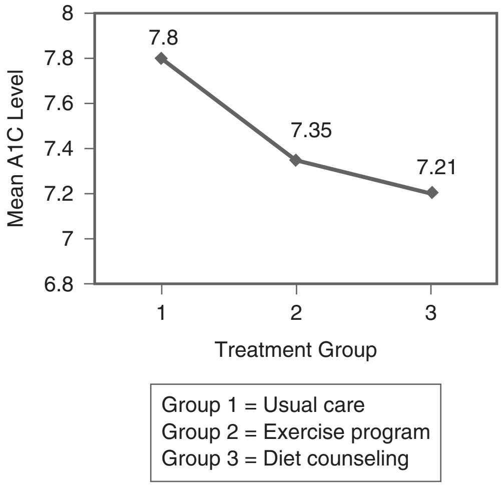


FIGURE 12.4 Findings from an ANOVA.

could not be rejected."[6] Therefore, the ANOVA distinguished exercise and diet from usual care, but did not find a significant difference in outcome between exercise and diet.

Factorial ANOVA

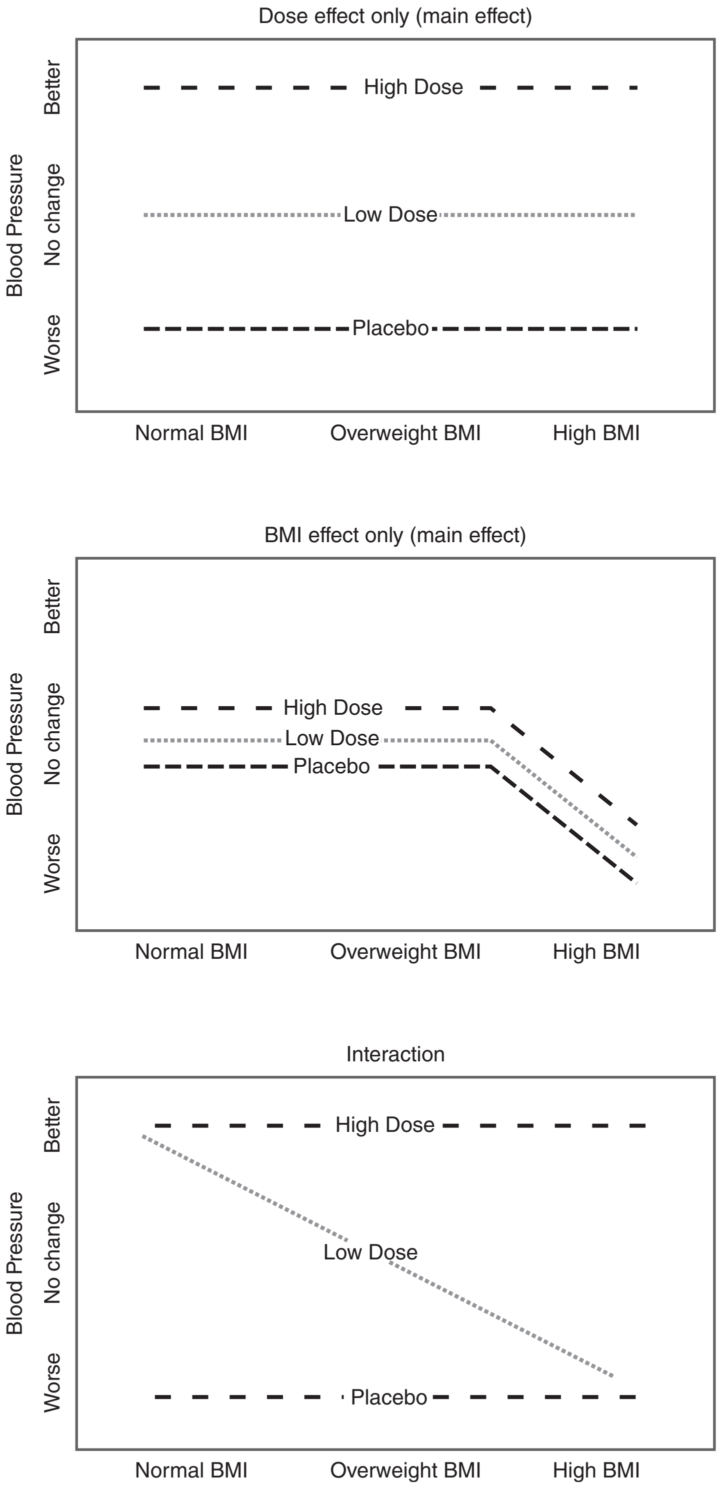
In contrast to the one-way ANOVA, the factorial ANOVA includes more independent variables (called covariates). The procedure allows investigators to test more hypotheses about how groups may differ. The researcher can check to see if the groups differ based on each independent variable separately. If an independent grouping variable is shown to be significant on its own, the result is called the *main effect*. Sometimes the influence of one independent grouping variable on the dependent variable is conditional on the *interaction* of another independent grouping variable. It is possible for each independent variable to have separate main effects on the dependent variable without any interaction. If an interaction does occur between the covariates, the separate effects are set aside, and the effect of one variable is interpreted for each level of the other independent variables. This interactive type of interpretation includes the assessment of *simple main effects*—what occurs as a result of the interaction.

In most cases, the covariate factors are fixed (not random) and are measured at two or more levels. For instance, an investigation of blood pressure medications may include groups treated with different doses of antihypertensive medication. The factor is the dose of medication, and the levels are the dosage categories that divide groups. For example, a new medication for blood pressure could be given in a high dose and a low dose. This single factor (medication) has two levels. If the investigators want to know if the effects of the medication vary by body mass index (BMI), then a second factor (BMI) can be added to the ANOVA. In the one-way ANOVA, the groups would be defined by only a single variable, such as the medication received. In a factorial ANOVA, however, the independent variables can represent differences in treatment along with variables that reflect additional individual differences between the groups. Because the number of comparisons increases compared to one-way ANOVA, the sample size in factorial ANOVA is usually larger than in a one-way ANOVA.

The factorial ANOVA allows investigators to partition the total sums of squares (SST), discussed previously, into more than the two components of a one-way ANOVA (between and error). The factorial ANOVA SST is divided into the model sums of squares and the error sums of squares. The model SS is divided into the SS for factor A, the SS for factor B, and the SS for the combination of factors A and B. Of course, this example is for a two-way factorial ANOVA. When three factors are included, the ANOVA is called a three-way factorial, and so on. In contrast to the one-way ANOVA, multiple F statistics are generated.

When interpreting a significant factorial ANOVA, one looks for significance and assesses the main effects and any interactions. If an interaction is discovered, the *simple main effects* are calculated. If there is no interaction between the factors, then the main effect of each factor is assessed using post hoc multiple comparison tests. Researchers often include graphical representations of the results, including main effects or interactions. **FIGURE 12.5** expands the previous example and includes different representations of the effects of two factors (medication and BMI), each with three levels, on blood pressure outcomes. The illustration depicts three different hypothetical outcomes: (1) the main effect of medication dose on blood pressure with no BMI effect, (2) the main effect of BMI with no medication dose effect, and (3) the interaction between medication dose and BMI.

When determining the effect size for a factorial ANOVA, researchers use statistical software to calculate ω^2, η^2, or an adjusted value called partial eta-squared,[7] for every significant F statistic. Although the interpretation of factorial ANOVA is complex, the procedure is frequently preferred to one-way ANOVA because it is useful in comparing groups across a variety of study designs.



Dose effect only (main effect)

BMI effect only (main effect)

Interaction

FIGURE 12.5 Factorial ANOVA.

Repeated Measures ANOVA

As discussed in the paired *t*-test section, measuring the same set of individuals more than once produces dependent groups of data. In the case of the paired *t*-test, two measurements resulted in two dependent groups of data. When more than two measurements of the same variable are taken from a single group of individuals (especially over time), the result is three or more dependent groups of data. The repeated measures ANOVA is, therefore, an extension of the paired *t*-test. For example, a single group of patients may be subjected to more than two treatments over time, or the treatment response to a single intervention may vary over time. Once again, the participants serve as their controls, thus reducing error variance and reducing the number of subjects needed. When the researcher seeks to explore differences occurring in individuals over time, the repeated measures ANOVA is the appropriate way to test for significance.

In the one-way ANOVA, there are two sources of variability (between groups and within groups). However, in the repeated measures ANOVA the variability is partitioned. The total sum of squares (SST) is divided into the sums of squares between people (SSBP) and the sums of squares within people (SSWP). The SSBP is less interesting than the SSWP. The SSWP reveals how the participants vary around their mean. The SSWP is partitioned into the sums of squares between treatments and the sums of squares due to random error. The SS between treatments allows for the comparison of the treatment means. This comparison is similar to the between-groups comparison in the one-way ANOVA.

Recall one of the assumptions underlying ANOVA (and other parametric tests) is equal variance. In a repeated measures ANOVA, the equality of variances is determined by something called sphericity. The sphericity of the data is assumed in repeated measures ANOVA. Researchers use a routine called Mauchly's test to check for sphericity and protect against a type I error.[3] If a lack of sphericity is identified, the researcher will make adjustments to protect the alpha level (*p*-value).

The repeated measures ANOVA table (see **TABLE 12.4**) is assembled similarly as previously demonstrated. The main difference is the labels are changed from between groups and within groups to between persons and within persons. Also, the sums of squares within persons are divided into the sums of squares between treatments (SSBT) and the sums of squares error (SSE).

Again, the purpose is to calculate an *F* ratio and compare it to an established distribution. If a significant *F* ratio is obtained, then post hoc testing helps to determine what differences have occurred between the individuals' measurements. The effect size can be calculated in the same manner as ANOVA. Partial η^2 or ω^2 interpretation guidelines can be used to assess the magnitude of the differences observed. One drawback of

TABLE 12.4 Repeated Measures ANOVA

Source	Sum of Squares	df	Mean Squares	*F*	*p*
Between persons	SSBP	$(n-1)$	MSBP		
Within persons		$n(k-1)$		$\frac{MSBT}{MSE}$	<.05 from the *F* table
Between treatments	SSBT	$k-1$	MSBT		
Error	SSE	$(n-1)(k-1)$	MSE		
Total	SST	$n-1$			

repeated measures ANOVA is the amount of missing data that may accumulate as studies increase in length (as in long-term longitudinal designs). Researchers should consider how to treat missing data in such circumstances. Also, when the participants receive different treatment conditions during the study, carryover effects from one treatment may influence the results obtained during other treatments.

Example

The following is an example of a repeated measures ANOVA assessing the efficacy of treatment over time. A group of patients with chronic venous stasis ulcers received a novel treatment that included electrical stimulation of their wounds over a 2-month period. Measurements of all patient wounds were taken at baseline, 2 weeks, 4 weeks, 6 weeks, and 8 weeks. The patients' wound healing scores were obtained by using a validated wound assessment instrument. The null hypothesis for the repeated measures ANOVA was that wound healing scores would be equal for all of the treatment periods. The *p*-value obtained was <.01, resulting in the rejection of the null hypothesis. Post hoc testing was required to determine how the time intervals differed in relation to wound healing. The investigators determined that the patients' wounds responded between baseline and 4 weeks and then did not change after that.

▸ Hotelling's T^2

Medical researchers may be interested in comparing groups using more than one dependent variable. When comparing two groups using multiple outcome measurements, Hotelling's T^2 is used. The test is named after mathematician Harold Hotelling.[8] In contrast to the *t*-test that compares the difference between two means, Hotelling's T^2 assesses the difference between two *mean vectors*. The null hypothesis is represented as H_0: $\underline{\mu}_1 = \underline{\mu}_2$ and matrix algebra is involved in the calculations. The underscore below the mu (μ) symbol indicates that the comparison is between mean vectors.

The symbol for a vector of means $\underline{M} = \begin{bmatrix} \text{mean } v_1 \\ \text{mean } v_2 \\ \text{mean } v_3 \end{bmatrix}$

The signal-to-noise ratio is created using the between-group difference in mean vectors and the *inverse of the covariance matrix*.[8] It is useful to know that the calculation of the test statistic uses a determinant to represent the value of each matrix. The Hotelling's T^2 is generated algebraically and converted to an *F* statistic for hypothesis testing.

When using Hotelling's T^2, the effect size is determined by something called the Mahalanobis distance (D^2). This statistic is the multivariate version of Cohen's *d*. The interpretation of the effect is dependent on the number of dependent variables included in the two-group comparison.

Example

In this example, researchers sought to determine if diabetic patients with congestive heart failure (CHF) are different from nondiabetic patients with CHF. The investigators determined that three outcomes of CHF are important: ventricular ejection fraction, serum creatinine, and diastolic blood pressure. The ranges of each of these outcome measures vary; however, the vectors of means for the two groups can be compared using Hotelling's T^2. In this case, the T^2 statistic generated by the computer is 3.52, the *F* statistic is 1.17, and *p* is .31. Therefore, the researchers failed to reject the null hypothesis that the vectors of means are equal for the two groups.

▸ MANOVA

The ability to examine group differences in multiple dependent outcome variables concurrently can be valuable. *Multiple analysis of variance (MANOVA)* is a variant of ANOVA that also allows for the study of multiple dependent variables. In this case, the comparison includes more than two groups. Clinicians are often interested in multiple related but differing outcomes. The dependent variables should be related to each other in some way without being redundant. For example, when evaluating the effect of different treatments on pulmonary function, the clinician may be interested in different indices than the forced expiratory volume in 1 second (FEV_1) alone. Using MANOVA, a linear combination of variables including FEV_1, forced vital capacity (FVC), and dyspnea scores can be assessed instead of a single metric.

Once again, the comparison of group means is replaced by a comparison of group mean vectors. The null hypothesis is represented as H_0: $\underline{\mu}_1 = \underline{\mu}_2 = \underline{\mu}_3 \ldots = \underline{\mu}k$. Notice the mean symbol in the following equation has a line below it—the notation is for a vector.

The symbol
for a vector
of means

$$\underline{M} = \begin{bmatrix} \text{mean } v_1 \\ \text{mean } v_2 \\ \text{mean } v_3 \end{bmatrix}$$

$$[\underline{M}G1][\underline{M}G2][\underline{M}G3]$$

Like ANOVA, the MANOVA can be constructed using one or more independent grouping variables. Therefore, it is possible to have a one-way MANOVA, a factorial MANOVA, and a mixed MANOVA or repeated measures MANOVA. Most statisticians test for homogeneity of the variance and covariance matrices because these are underlying assumptions in MANOVA. A test called Levene's test checks the null hypothesis that the error variance of the dependent variables among the groups is equal.[3] A test called Box's test checks the null hypothesis that the covariance of the dependent variables is equal.[9] These procedures are merely examples of how statisticians evaluate the equal variance assumption in a multivariate case.

The *F* value in MANOVA is a multivariate *F* and can be produced using different named tests of significance. The names to be familiar with are Pillai's trace, Wilks's lambda, Hotelling's trace, and Roy's largest root. Each of these tests will produce an *F* value with an associated *p*-value to judge whether the results obtained are statistically significant.[9]

If the overall MANOVA results are significant, a separate ANOVA can be completed for each dependent variable, with post hoc testing in each case, for interpretation. Discriminant function analysis can also be used as an interpretive aid.

Example

Assume the investigators in the CHF example want to compare outcomes among six different causes of CHF, rather than diabetes (as in the Hotelling's T^2 example used previously). Each of the six causes of CHF comprises a separate group. The outcomes of interest are ventricular ejection fraction, serum creatinine, and diastolic blood pressure. The MANOVA will generate a series of *F* statistics to test the null hypothesis that the vectors of means are equal for the six causal groups. In this example, Wilks's lambda, Pillai's trace, Hotelling's trace, and Roy's largest root all produce *F* statistics that are significant with *p* values $<.001$. This result only alerts investigators that some differences exist between the groups. After finding significance using the MANOVA, the researchers must perform individual ANOVAs for each of the outcome variables and post hoc testing for any of the ANOVAs that are significant. In this example, the separate ANOVA tables (**TABLES 12.5**, **12.6**, and **12.7**) reveal ventricular ejection fraction is the only outcome that includes a significant

TABLE 12.5 Source Table for Ventricular Ejection Fraction

Source	SS	df	MS	*F*	*p*
Between groups	6762.01833	5	1352.40367	17.47	0.0000
Within groups	524,634.25	6776	77.4253615		
Total	531,396.268	6781			

TABLE 12.6 Source Table for Serum Creatinine

Source	SS	df	MS	*F*	*p*
Between groups	0.266260806	5	0.053252161	0.39	0.8560
Within groups	925.197266	6776	0.136540329		
Total	925.463527	6781			

TABLE 12.7 Source Table for Diastolic Blood Pressure

Source	SS	df	MS	*F*	*p*
Between groups	574.334327	5	114.866865	0.91	0.4756
Within groups	857,943.362	6776	126.708516		
Total	858,517.697	6781			

difference between groups. (Note the *p* values for each ANOVA table.)

Because the ANOVA for ventricular ejection fraction is significant, the next step is to look at the associated summary table and post hoc tests (**TABLE 12.8**).

Visual inspection of the summary table reveals that groups 4 and 5 have lower ejection

TABLE 12.8 Summary Table for Ventricular Ejection

CHF Etiology	Mean Ejection Fraction	SD
1	28.9	8.6
2	29.5	9.2
3	29.5	9.4
4	**26.6**	9.0
5	**25.8**	9.4
6	28.5	9.4
Total	28.5	8.9

TABLE 12.9 Bonferroni Comparison Table of Ventricular Ejection Fraction by CHF Etiology Group

	Group 1	Group 2	Group 3	Group 4	Group 5
Group 2	0.646295				
Group 3	0.632383	−0.013913			
Group 4	**−2.31245***	**−2.95874***	**−2.94483***		
Group 5	**−3.05831***	**−3.7046***	**−3.69069***	−0.74586	
Group 6	−0.379055	−1.02535	−1.01144	1.93339	2.67925

*The significant *p* values occur when comparing groups 4 and 5 with groups 1, 2, and 3.

fractions than the other groups. The post hoc tests such as Bonferroni, Sidak, and Scheffé provide comparison tables (**TABLE 12.9**) to show which of the comparisons are meaningful.

Summary

This chapter reviewed the use of common statistical tests assessing differences between groups. In each case, a signal-to-noise ratio is generated to produce a test statistic that can be compared with a normalized distribution to determine if the differences occurred by chance. This statistical approach to hypothesis testing can be used for various study designs, including simple two-group comparison and complex multivariable, multilevel comparisons. However, hypothesis testing alone is insufficient when reviewing the results of healthcare studies. The researcher must consider the effect size generated by these comparisons. The results should also be contextualized and assessed for clinical meaningfulness.

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CHAPTER 13

The Results Section

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CHAPTER OVERVIEW

This chapter discusses how to present results from data analyses. For most manuscripts, the Results section is the shortest and most graphically displayed. It is important that findings, particularly key findings, be presented clearly and logically. The Results section should consist of findings from the study presented factually, without remarking on them. Commenting on the findings belongs in the Discussion section. Graphs, charts, and tables or a combination of these are often used to present results, the selection of which depends on the amount and type of data presented. The Results section (sometimes referred to as the Findings section) is an important part of a research report, as this is where the author(s) indicates findings that support or reject the proposed hypotheses or research questions. The preceding sections of a research report are designed to provide a foundation for what is shared in the Results section. Additionally, findings in the Results section should align with the preceding Materials and Methods (or Methodology) section.

LEARNING OBJECTIVES

- List and define what information is included in the Results section.
- Describe table, graph, and image construction.
- Discuss the importance of the Results section.

Introduction

The Results section should present key findings related to the research question, *without* commenting on the meaning or importance of the data as it relates to existing literature. It is the purpose of the Discussion section to convey these concepts to the readers. The Results section is typically the shortest section of the research manuscript. The section should be clearly and succinctly written and in the past tense. For ethical reasons, key findings that accurately convey results should be reported, not only those supporting or rejecting the hypotheses. Information about or descriptions of what was done in the study regarding the enrollment of the study population, data collecting and any interventions being tested belong in the preceding Materials and Methods (Methodology or Design) section and should not be included or repeated in the Results section.

The reported results must be consistent with the methodology and data analyses. As mentioned above, only factual information should be included in the Results section, and findings should be conveyed using a neutral tone to allow readers to form their conclusions. For example, reporting that the systolic blood pressure decreased on average 10 mm Hg after administration of agent *X* is clearer than reporting that the mean systolic blood pressure was 120 mm Hg after administration of agent *X*. Ultimately, the Results section is the central element of the research report, as it provides the basis for what follows and, most importantly, the interpretation of meaning relative to existing literature.[1] A common beginners' mistake is reporting raw data rather than summarizing key findings. Typically, the tables, graphs, or charts provide the complete picture of the study's findings. Include highlights in the main text, rather than repeating everything presented in the tables, figures or charts. The following excerpts provide an example of a poorly written segment in the Results section and a contrasting improved segment:

> *Problem: Facts Without Interpretation*
>
> *The mean resting pulse rate for the 10 control subjects was 74 ± 4 (SD) compared to the 12 athletes with a mean resting pulse rate of 66 ± 5 beats per minute.*
>
> *Improved Presentation*
>
> *The mean resting pulse rate was 11% lower in the 12 athletes than the 10 control subjects: 66 ± 5 (SD) versus 74 ± 4 beats per minute, $p < .05$).*

Note that the magnitude of the difference (11%) is reported as well as the probability value indicating that the difference was statistically significant. The first example is ambiguous and leaves it to the reader to determine the meaning of the data, whereas in the second example the author makes clear what is important about the finding.

The Results Section Text

The Results section typically begins with a complete description of the characteristics of participants, including demographics or clinical features so the reader has a good understanding of how representative the study sample was relative to the entire population. Numbers, percentages, and central tendency statistics should be used to describe the study sample. An example of this part of the section might read: "Fifty-two percent (78/149) of the healthcare professionals responded to the survey. Twenty questionnaires were returned with destination unknown (13.4%), and 51 did not respond (34.2%). Of the respondents, 33 were male and 45 were female. The average age was 34 years (SD = ± 6.5)."

After describing the study sample, the researchers report the results of statistical analyses with sufficient detail to permit the reader to determine that appropriate analyses were conducted to support or reject the tested hypothesis and to ensure the study can be repeated using the same approach. For descriptive research, frequencies, ranges, and measures of central tendency should be reported. For quasi-experimental or experimental research, inferential, associational, or statistical tests consistent with the study design should be included, such as the test statistic, the direction, and the level of probability. Confidence intervals and or effect sizes should be reported, to further support the study findings in terms of statistical significance.[2-5]

The word *significant* in discussions of data must be used carefully. *Significant* means "statistically significant" or "clinically significant" when written in the healthcare literature. Some authors see events or numbers of subjects affected as significant because of the event, intervention, treatment, or effect. In the Results section of the manuscript, something is significant only if the result is statistically significant according to the data analysis.

In addition to reporting significance related to hypothesis testing, sufficient information about the statistical test must be provided to allow the reader to understand that the preferred method for reporting the statistical test used.[6] This detail may be particularly important if a novel analytic approach was used or if the procedure is considered controversial. It may be appropriate to include such descriptions in the Methodology section with sufficient justification for the readers to judge the appropriateness of the tests used. Always assume that readers have a working knowledge of statistics and research design. Finally, the extent to which the hypotheses that were supported should be indicated in the Results section, and clearly linked to the null hypotheses or research questions or alternate hypotheses as appropriate. Ultimately, the data should speak for themselves.

Tables and Figures

For the sake of clarity and brevity, tables and figures are typically used to show research results. These are often produced before the author begins writing the text of the Results section. Selection of how to present research findings depends on the amount and type of data shown. For simple studies, charts and figures provide meaningful and compelling displays of the findings. A complex study may need to use tables to convey all relevant data. Follow the publishing constraints of the target journal.[7] When reporting findings in the text, avoid the temptation of making the topic sentence (first sentence of the paragraph) a reference to a table or figure. For example, "Table A presents the means and standard deviations for the control and experimental groups." This is an inappropriate topic sentence and provides no useful information. A better example is "The experimental group showed a 10% improvement in scores over the control group (Table A)."

Many commercial software programs (e.g., Microsoft Excel, Harvard Graphics, SPSS) make it fairly easy to create tables and graphs, often without having to re-input data. Because tables and figures are more expensive to reproduce (compared to the body of the text), it is important to use only those graphic elements that are most important to the primary findings.

Some tables describe the study sample (see **TABLE 13.1**), compare groups (see **TABLE 13.2**), or show correlations (see **TABLE 13.3**). The types of analyses performed on the research data dictate the format for display in a table. For qualitative or nonexperimental studies, tables are sometimes used to summarize or compare textual information (see **TABLE 13.4**). For experimental studies, tables like Table 13.1 are used primarily to demonstrate that the independent variables for the control group and experimental group are not significantly different, though in the example Table 13.1, no statistical tests are shown.

TABLE 13.1 Demographic Profile for OT Class of 2016 ($n = 20$)*

Variables	Mean	SD	Median	Range
Age	28.10	5.44	26.50	23–44
Previous healthcare experience (months)	21.95	10.97	20.50	12–60
High school GPA†	3.09	0.42	3.00	2.25–3.90
Undergraduate GPA	3.36	0.31	3.32	3.00–3.90

†GPA = grade point average.

TABLE 13.2 Comparison of Job Profiles for PA Classes of 2016 and 2017[*,†]

Variables	**Class of 2016 (*n* = 12)**		**Class of 2017 (*n* = 18)**	
Practice Characteristics	***n***	**%**	***n***	**%**
Specialty				
Family medicine	6	50	6	33
Pediatrics	1	8	4	22
General internal medicine	1	8	0	0
Emergency medicine	3	25	2	11
General surgery	1	8	3	17
Other	0	0	2	11
Location				
Urban	5	42	8	44
Suburban	5	42	7	39
Rural	2	17	2	11
Practice type				
Solo	1	8	5	28
Group	4	33	7	39
Hospital	5	42	5	28
Other	2	16	0	0
Unknown	0	0	1	5

[†] Percentages may not total 100 because of rounding.

Tables should be clear enough to stand alone without explanation in the text. Although tables can be helpful for the organization and display of important findings, they can be confusing if they are not used and/or constructed appropriately. All relevant information for the type of statistic reported (e.g., test statistic, degrees of freedom, probability

TABLE 13.3 Intercorrelations Among Educational Outcomes for Health Professions Students ($n = 50$)*

	High School GPA	College GPA†	Basic Science GPA	Clinical GPA	Practice Exam	Certifying Exam
High school GPA	—	0.77**	0.54*	0.36	0.12	0.11
College GPA		—	0.79*	0.23	0.34*	0.17
Basic science GPA			—	0.22	0.27	0.21
Clinical GPA				—	0.56*	0.62*
Practice exam					—	0.81**
Certifying Exam						—

Note. GPA = grade point average; *$p < .05$. **$p < .01$.

TABLE 13.4 Comparisons of Common Cardiac Murmurs*

Diagnosis	Location	Timing	Pitch	Quality
Aortic stenosis	Second right intercostal space, sternal border	Midsystolic	Medium	Coarse
Aortic regurgitation	Base, patient seated and leaning forward	Early diastolic	High	Blowing
Mitral stenosis	Apex, patient in left lateral decubitus position	Diastolic	Low	Rumble
Mitral regurgitation	Apex	Holosystolic	High	Blowing

Data from Seidel HM, Benedict G, Dains JE, Ball JW. *Mosby's Guide to Physical Examination*, 4th ed. St. Louis, MO: Mosby-Year Book; 1998:467–471.

value, and direction in the case of inferential statistics) must be included. Because readers tend to make comparisons first horizontally from left to right, primary comparisons in tables should be shown horizontally.[8] **TABLE 13.5** lists additional general guidelines for the use and construction of tables.

Graphs, charts, pictures, including radiographs, computer-generated images, diagrams, flowcharts, drawings, and the like are considered figures. The variety of types of graphs includes line graphs (see **FIGURE 13.1A**), histograms (see **FIGURE 13.1B**), bar graphs (see **FIGURE 13.1C**), and scatterplots (**FIGURE 13.1D**).

TABLE 13.5 Guidelines for the Construction of Tables*

1. Choose a clear and specific table title so there is no confusion about the contents.
2. Number tables consecutively using Arabic numbers from the beginning of the report and label them accordingly.
3. Use subheadings for the columns and rows. Format cells so the data are clear and easy to read; often alignment on decimals is preferred.
4. Limit your information to include only material related to your descriptive title. For example, do not mix sample demographics with inferential statistics.
5. Do not explain your table in the text; it should speak for itself; however, the table must be identified in the text (e.g., see Table A).
6. Use table formats that are consistent and that conform to the publisher's guidelines. Check with the publisher in advance or consult the "Instructions to Authors" to determine whether tables and figures should be submitted separately or incorporated within the text.
7. Avoid excessive lines. Vertical lines for columns are not needed, but there should be sufficient space between the columns so the table is easy to read. Also, tables should be limited to one page.
8. Be sure to include appropriate units of measure (e.g., mg/dL).

Data from Wiersma W. *Research Methods in Education: An Introduction*, 7th ed. Needham Heights, MA: Allyn and Bacon; 2000:393–394.

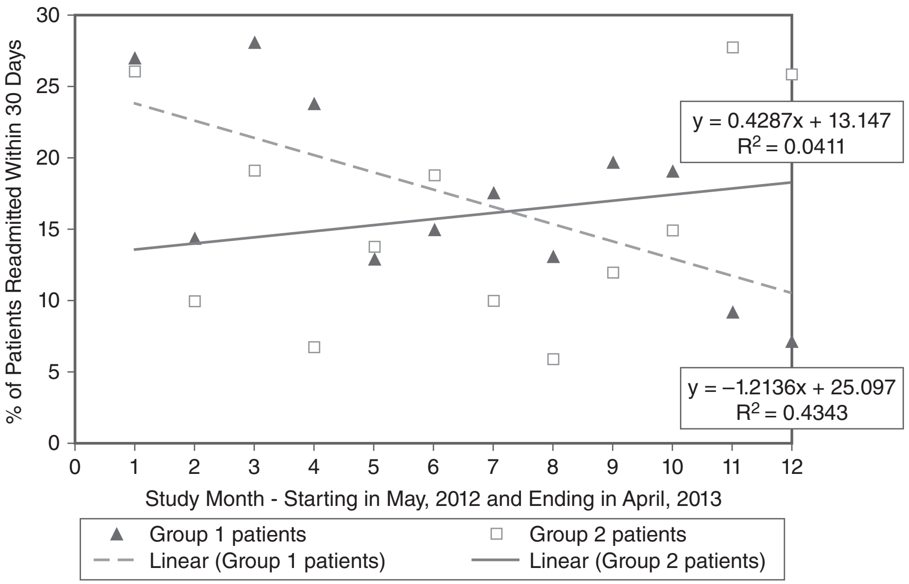

FIGURE 13.1A Example of a Line Graph*.

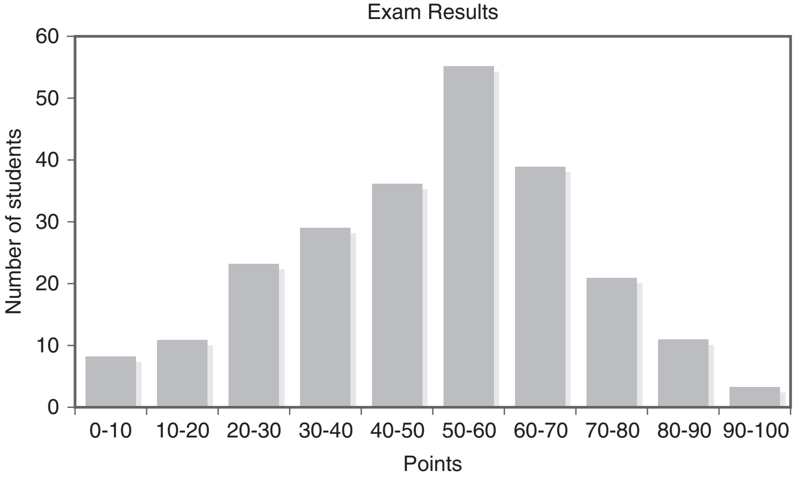

FIGURE 13.1B Example of a Histograph*.

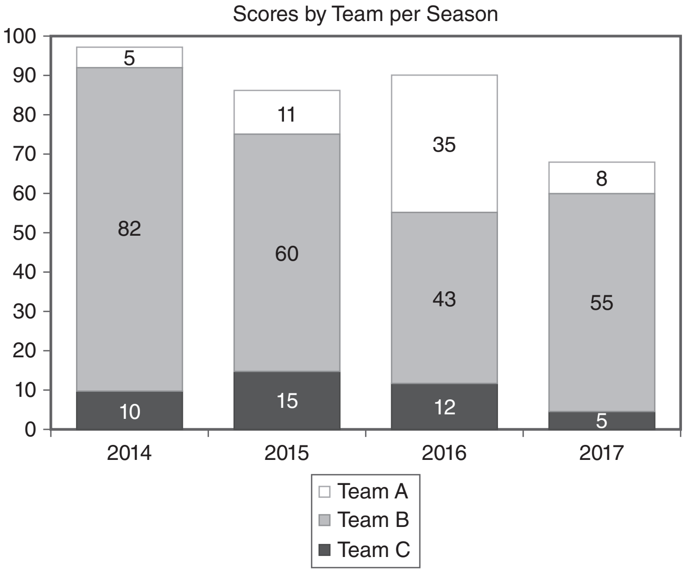

FIGURE 13.1C Example of a Stacked Vertical Bar Graph*.

Many journals have specific directions for the construction and display of tables, graphs, and figures. When submitting work for publication, be sure to follow the journal's "Instructions for Authors." Editors do not want to spend time correcting such items, and failure to follow instructions may result in rejection of the manuscript.

Generally speaking, polygons and histograms are used to plot frequency distributions. Bar graphs are different from histograms in that

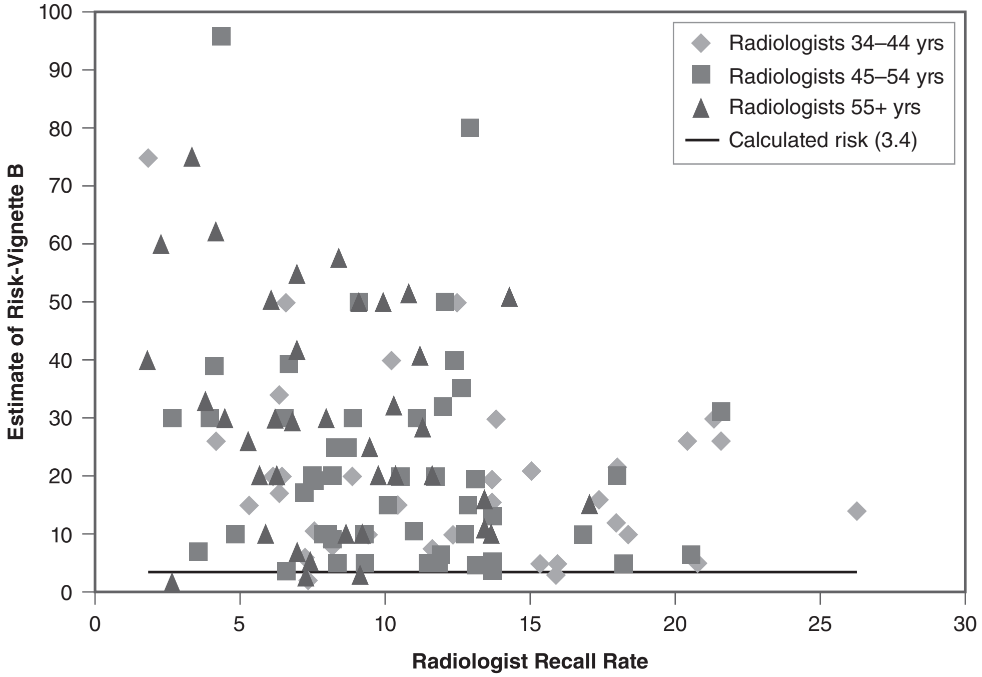

FIGURE 13.1D Example of a Scatterplot*.

the columns are separated; these graphs are best used to show comparisons between two or more groups. Bar graphs are frequently used when the independent variables are categorical. When developing graphs (particularly bar graphs), care must be taken to ensure that proportions of the width, height, and scale provide an accurate display of the data and are not visually misleading because of dimensions of the graph. Line graphs are used to show the relationship between two quantitative variables.[9] The intersection of the *x* and *y* axes in the lower left-hand corner is typically zero (0). If there is a discontinuity in an axis, it should be represented by a pair of diagonal lines (//) to show the missing portion, but this should be avoided if possible. The dependent variable is plotted on the vertical (*y*) axis.

Many software programs create graphs using color, but most journals reproduce the graphs in black, white or grey shades. Therefore, it is important to ensure sufficient contrast exists between adjacent bars. Keep in mind that commercial software contains certain features (e.g., three-dimensional bar graphs) that enhance the appearance of a PowerPoint or Keynote presentation but may not reproduce well when the size is decreased, and colors are converted to black, white, or grey. The American Medical Association recommends a shading contrast of at least 30%.[8] In addition to using shading to distinguish bars or pie chart sections, many commercial programs allow different patterns such as cross-hatching. Pie charts are used to show percentages or proportions of different quantities and are used to display results of descriptive research. **TABLE 13.6** provides a quick review of general guidelines for the construction of graphs.

When presenting results in a paragraph or graphically, double check the numbers for accuracy. Make sure that graphs present results clearly. An inadvertent mistake in one number could make readers uncertain about all results. More than one error may make them ignore everything, even if the conclusions and interpretations are correct.

TABLE 13.6 General Guidelines for Developing Graphs*

1. Be sure the graph is labeled as a figure and has a self-explanatory title.
2. Select the proper type of graph based on the data, statistical analysis, and clearest presentation to the reader.
3. Refer to figures in the text and number them consecutively. (Tables and figures are numbered separately.)
4. Be sure there is enough spacing for ease of interpretation and that the grid is scaled proportionately.
5. Check spelling (including caption) and ensure data were entered and plotted correctly.
6. Ensure there is sufficient contrast or pattern difference to clearly separate segments of pie chart or bars on the bar graph. Avoid three-dimensional or other special effects.
7. Check with the publisher for guidance on overall size, font size, resolution, and style specifications.
8. Include legends if necessary, and define abbreviations.
9. Update permission from the copyright holder for reproductions or adaptations from other sources. Be sure the source is noted.
10. For photographs and other illustrations, be sure to mark "TOP" so the publisher has the proper orientation for typesetting and layout. In addition, be sure these items are labeled and identified with your name and article title in case they are separated from the manuscript.

Note: This may not be necessary if the graphic is imbedded in the manuscript.

Summary

The Results section of the report is used for presenting the results of the statistical analyses. The section must be clear and concise. Tables, graphs, and other figures should be used to present data in a way that makes the results easily read and understood, and so that they invite interpretation. The Results section also provides the basis for a decision on the rejection or retention of null hypotheses and/or whether research questions were supported or answered. The Results section is free of author (or any other) bias. Think of this section as a place for the factual presentation of the research results.

References

1. Hofmann AH. *Scientific Writing and Communication: Papers, Proposals and Presentations.* New York: Oxford University Press; 2010:265.
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6. Creswell JW. *Educational Research: Planning, Conducting, and Evaluating Quantitative and Qualitative Research.* Boston, MA: Pearson; 2012.

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* Note that all data portrayed in the tables and figures for this chapter are fictitious and are not intended to represent any actual research study or source. Readers should consult the "Instructions for Authors" in journals to which they intend to submit manuscripts for specific guidelines and requirements.

7. Bailey DM. *Research for the Health Professional: A Practical Guide.* 2nd ed. Philadelphia, PA: F. A. Davis; 1997:193.
8. American Medical Association. *AMA Manual of Style: A Guide for Authors and Editors.* 10th ed. New York: Oxford University Press; 2007:84.
9. American Psychological Association. *Publication Manual of the American Psychological Association.* 6th ed. Washington, DC: American Psychological Association; 2010:151.

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CHAPTER 14

The Discussion Section

Richard R. Rahr, EdD, PA-C
J. Dennis Blessing, PhD, PA

CHAPTER OVERVIEW

The Discussion section of a manuscript is where the author/investigator can state their interpretations, conclusions, and opinions about the research project and its results. It is in the discussion section where the investigator can provide answers to the questions posed in the introduction. Of all the sections of a thesis, dissertation, or manuscript for publication, this section most reflects the author's ability to synthesize experimental results. This section is the place where opinions, views, and meaning are presented.[1]

The Discussion section may or may not contain several subsections. These subsections may be referred to by different titles, such as summary, implications, interpretations, or recommendations. The section should also include a closing paragraph(s) labeled "Conclusions" or something similar to that term. The section and subsections titles depend on the type of work being produced, as well as local and publication requirements. The author has some discretion on what subsections to include in the Discussion section. This section should center on the importance of the results and the implications and application in patient care, education, or the healthcare professions.[1]

LEARNING OBJECTIVES

- List, describe, and define the components of the Discussion section.
- Define the importance of the Discussion section.
- Define and describe study limitations.
- Define and discuss the importance of the Recommendation section.

Introduction

The traditional Discussion section of a research report covers the following areas: implications, limitations, discussion, bias considerations, recommendations, and conclusions. A review of several "how-to" research books reveals that similar descriptors, such as summary, interpretation, and analysis, are used in the Discussion section. Even the order of the subsections varies. This chapter focuses on the terms most commonly used in the research literature; however, local or publication requirements may differ.[2]

The Implications Subsection

In the Implications subsection, the author explores the meaning of the research results. This is the author's opportunity to think critically about the results, draw conclusions, or make inferences; for example, what changes are indicated in clinical practice based on the research findings? What do the results mean to health care and society? Even if there were no statistically significant findings related to the research study's hypotheses or questions, the research effort could still have meaning. One inference from statistically nonsignificant results may be that current practice is supported by the data and results. The recommendations for such studies may well be to make no changes and to continue with the current best knowledge. If the investigation yielded significant results, then an author can take the opportunity to discuss why and what that means in light of what is known. If there are significant findings that have strong implications for practice or the fund of knowledge, a new approach to the problem or a practice change can be recommended. Remember, major changes in healthcare practice and theory are seldom based on a single study unless it is a very large, well-designed, and carefully controlled investigation. Meta-analysis, which is the integration and evaluation of several or many independent research studies, is now considered one of the highest levels of research sophistication, particularly for evidence-based practice. Even in evidence-based analysis, however, questions are often raised that require further investigation.[1]

The implications of the study may point out the potential value of a finding or the need for replication or modifications in a subsequent study to strengthen the research results or findings. When an investigator believes the results have important implications, those results should be stated in positive terms. Rational arguments based on data and analyses, particularly when contradicting accepted dogma or theory, must be presented clearly.

Here is an example of an implication: Study antibiotic *X* increased the effective cure rate for osteomyelitis by 25 percent over the currently available drug treatment. If antibiotic *X* had no major side effects, then it would certainly be recommended for the treatment of osteomyelitis. If an investigator found that giving antibiotic *X* with the addition of daily treatments in the hyperbaric chamber made no significant difference in the overall treatment outcomes, then the recommendation would be that the additional treatment not be used in tandem. The investigator must explicitly state the implications for clinical treatment based on the findings.

The meaning and limitations of statistical analysis should be considered when stating the implications of the investigation. Here is an example: If the Pearson product-moment statistical test is used to measure a variable, and the analysis results in a significant correlation of $r = 0.70$, then this would seem to be a good correlation. However, further analysis using the Pearson's correlation r with a second statistical analysis called the r^2 (the coefficient of determination) returns a result of $r^2 = 0.49$. This second statistic accounts for only 49 percent of the correlation variance. The fact that 51 percent of the research study variance is not explained should cause a conservative interpretation of the implications and recommendation decisions. All discussion must make sense of the statistical analysis and the results.

Ultimately, the Implications subsection is where the author makes a case for the study and its results. Avoid including information or data that do not belong in the subsection. The investigator's best critical thinking skills should be used to form the implications with awareness of the current literature about the study results. This is one reason the methodology is so important. The well-designed and sound methodology allows strong support for the implications. Implications, regardless of type or nature, should have practical and clinical significance and should be supported by the research findings.

The Limitations Subsection

The Limitations subsection of the Discussion section is of utmost importance. The study's weaknesses (or limits) must be addressed in the presentation of the research. Problems or limitations should be recognized and pointed out by the researcher so that the overall value of the study can be considered. This explanation may allow those limitations to be avoided if the study is replicated. The researcher may realize, in retrospect, that there were flaws in the methodology.

All studies have limitations. Putting these limitations in front of the reader gives credence to the conclusions and the investigator's understanding of the study. Recognizing study limitations must be considered and included when making conclusions about the research project. Recognizing and stating the limitations of the work ultimately strengthens the work and its impact.[1]

Authors should clearly state to whom and in what situations the research study's findings or outcomes can be generalized and applied. Again, recognizing and considering limitations is very important in understanding the application or meaning of the study's findings. How well did the sample participants represent the population? The researcher may have inadvertently attracted or recruited only a certain subgroup of the intended population. For example, even though the researcher sought a representative sample of both men and women of various age groups, perhaps only women within a certain age range were willing to participate in the study. The findings and conclusions must take this limitation into consideration. Also, can the data from such a study be generalized to the whole population? For some investigations, a pilot study may reveal some of these problems (limitations) and help guide the methodology. A well-designed, meticulous study usually has very few limitations.

The Limitations subsection should also discuss the randomness of the sample selection and the potential for error in the sampling. Having an experienced researcher as a guide and mentor can assist any new (or even experienced) investigator in developing a study that is as strong as possible within the ever-present constraints of practice or educational setting. Consideration must be given to whether an intervening variable or research effect (e.g., the Hawthorne effect) could be responsible for the results.[2]

If limitations are identified or recognized in a research project, investigators must be honest and forthright about those limitations. Such forthrightness gives the researcher, the research project, and its outcomes greater credibility and potential for acceptance. If readers are informed of limitations, other researchers can attempt to avoid these limitations in similar, future studies.

The Discussion Subsection

The Discussion subsection of the Discussion section (appears redundant, but it is a subsection in the larger section) is used to meld together the research report, the interpretation of the results, the implications, and the study's limitations into an objective presentation. In previous parts of the research report, there is no room (or justification) for the author's subjective thoughts and insights. The discussion subsection is refreshing in that it allows and encourages authors to give their view of the impact and importance of the research outcomes. This is the author's opportunity to place the study in the ongoing conversation and context of the current literature. The author can interject subjectivity based on previous clinical and research experiences and wisdom (expert opinion). How did the significance or non-significance of the data relate to the conceptual framework of the literature that was reviewed? This is where the author gets to answer that question, in their opinion, based on the investigation.

In this subsection, readers expect to be apprised of some practical application of the research findings. The author demonstrates their research knowledge and wisdom here. A clinical example could be the matching of patients with providers of the same gender. Is the effectiveness of the encounter perceived to be better by patients? By providers? Again, several other factors can influence these perceptions. In the Discussion subsection, all of these factors can be explored in light of the research findings.

In the Discussion subsection, the author may want to discuss the characteristics of survey tools, limitations, generalizations, statistical methods, and bias considerations of the research project. Ultimately, this part of the report is used to critically discuss the study and evaluate research outcomes and their impact. In some formats, the Discussion section is the last subsection of the text.[1]

The Recommendations Subsection

The Recommendations subsection of the Discussion section usually states the author's ideas on the future research requirements based on the outcomes of the current study. For example, the author may include suggestions to expand the existing research by adding more subjects to the current research plan. The author can also suggest "next step" studies. Other recommendations may include developing a new research design, using a new data collection instrument, or addressing the gaps or weaknesses in the study. Recommendations may include making the study a double-blind crossover model, adding a control group, or suggesting an outside independent investigator repeat the same study to determine if the results can be replicated. The overall purpose of the Recommendations subsection is to alert the reader that additional questions need to be asked and answered. The author should avoid providing so many recommendations that the most important ones are obscured. As elsewhere, the author should strive for relevance, clarity, and brevity in this subsection.[1,2]

The Conclusions Subsection

This element is usually the last section of the paper, and it is usually brief. The Conclusions subsection of the Discussion section should begin with a brief restatement of the aim(s) of the study and the major research questions or hypotheses. Following that, the author should state the major findings of the study, using a format that can be easily followed. Here is an example:

> *This study demonstrated that patients who are treated for chronic severe pain with analgesic medication administered around the clock rather than on a PRN schedule had a higher level of functional status. Based on this finding, a major implication may be to change the treatment protocols to a regular schedule rather than PRN medication administration for patients with chronic severe pain.*

Clearly stated implications for practice, when backed by sound research findings, help to build an evidence-based practice, and improve the patient care.

A high-quality contrast and comparison of the results with the relevant underlying literature is expected. For example, the author can point out that the same or similar research findings have been reported. The author may wish to restate the strong and weak points of the research study; however, redundancy should be avoided unless a point is restated purposefully. The Conclusions subsection also provides the author the opportunity to share personal opinions and experiences that highlight and emphasize the impact of the research study. This should be done carefully; these comments by the author must be clearly related to the current study and should not merely be the author's general opinion. The overall practical value of the information presented in research studies is important in the context of healthcare practice.[2]

The Conclusions subsection is much like a closing abstract, but with a bit more detail than is allowed in the Abstract section. This subsection should provide a complete, but concise, overview of the research study while bringing the Discussion section to a close. In summary, **BOX 14.1** presents key elements the Discussion section should include, and **BOX 14.2** provides reminders of pitfalls to avoid in this section.[2]

BOX 14.1 Key Criteria for the Discussion Section

State what the research findings contribute to the understanding of the defined problem or question.
Be specific about implications for practice or society.
Describe how the findings fit into the present body of knowledge.
State how the findings support, enhance, or contrast with prior research findings.
If the findings are novel or in contrast to accepted norms, strong support is needed for the interpretations.

BOX 14.2 Pitfalls to Avoid in the Discussion Section

Drawing conclusions or formulating implications that cannot be clearly supported by the research findings.
Providing so many recommendations for further study that the most important recommendations are lost.
Having an apologetic tone when describing limitations or study design weaknesses. Be matter of fact.

References

1. Hissong AN, Lape JE, Bailey DM. *Research for the Health Professional: A Practical Guide*. 3rd ed. Philadelphia, PA: F. A. Davis; 2015.
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SECTION 4

The Research Process: Writing and Interpretation

CHAPTER 15 References 205

CHAPTER 16 Writing and Publishing in the Health Professions 215

CHAPTER 17 Interpreting the Literature. 237

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CHAPTER 15

References

Laura Zeigen, MA, MLIS, MPH, AHIP

CHAPTER OVERVIEW

This chapter discusses the larger philosophical framework around the role of citations and attribution, as well as an investigation of the basic functions of tools that can assist in the process of proper and thorough citation.

LEARNING OBJECTIVES

- Describe the reasons for taking the time to properly cite any sources utilized in the creation of scholarly or other professional writing.
- Identify major citation styles in the health sciences.
- Identify major elements of references.
- Identify resources that can be referenced for help in adhering to citation styles.
- Describe the use of copyrighted material, fair use provisions, public domain, and plagiarism.

Becoming Part of the Scholarly Conversation

At first glance, the reasons for why instructors, journal publishers, and others insist on using proper citations might seem unclear. At best, laboring over a well-done reference list can seem like a minor side note to the actual writing and, at worst, can be an exercise in frustration with the pedantics of citation style formatting. This frustration often occurs at 2 a.m. the night before a paper is due. During such moments, why should we even care about creating accurate citations within a thorough references list? The answer should be clear by the end of this chapter.

General Concepts About Joining the Scholarly Conversation

There are a number of important reasons why learning how to attribute resources consulted in research process properly is vital. There are more profound reasons for taking the time to cite properly that go far beyond the course or publisher requirements.

Proper citing establishes a context for the author's arguments. Knowing what a person used in constructing their arguments helps the reader understand where the author is going. All work is done in relation to others, and without citations, the work a person is putting forward is decontextualized. Knowledge and scholarly communication are socially constructed. Participating in a disciplinary community necessitates respecting the communication conventions of that community. By not citing properly, the author is declaring their unwillingness to participate or engage in one's scholarly community in a respectful way.[1] Learning how to communicate with others in the same profession in standardized ways generates efficient and effective communication across that community.[2] Standardizing communications works in clinical settings as well. For example, clinical providers utilize frameworks such as SOAP notes to standardize their communications about patients.[3]

The purpose of any citation style is to transparently reflect the resources one has used to make conclusions and as supporting evidence for an argument. By including the references used in establishing an argument about evidence, one invites any reader into the scholarly conversation to examine these same resources and make their own conclusions.[4] Transparency and the invitation to replicate, or find something different, lay at the heart of scientific inquiry.

Documenting Sources Used in the Research and Synthesis Process

Within the conceptual framework of the five steps of evidence-based practice, documenting sources used in the research process could be considered part of the **APPLY** stage that occurs after the ASK, ACQUIRE, and APPRAISE steps (**FIGURE 15.1**).

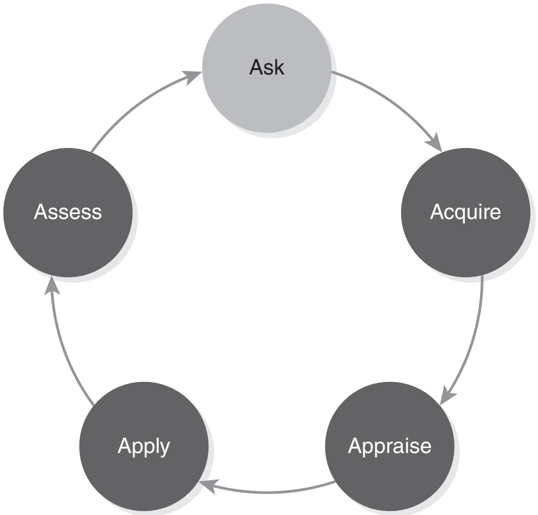


FIGURE 15.1 5 Steps of EBP – introduction to evidence-based practice tutorial from duke university medical center library.

While researching a question and developing an understanding of the existing research and background literature on a topic, researchers should start synthesizing their own ideas about how their issue fits into existing work. This is the "synthesis" stage shown in **FIGURE 15.2**.

Documenting citations utilized in the thinking and writing process helps the reader understand which sources the author drew on to come up with particular ideas or pieces of their argument. Citing helps ensure that other authors in a particularly scholarly conversation are credited for their work. Citing does not consist of just copying and pasting sentences from different resources and then citing them. Ideas should be brought together in true synthesis, with citations being used to help support the assertions made by the author (**FIGURE 15.3**).

Constructing either a bibliography (or references list) at the end of a manuscript or including in-text or footnote citations on each page are the two major ways of providing documentation of works consulted during the background research process. Reviewing the list of references you have generated allows the reader to understand the context you used to make your assertions. The list also allows them to locate and investigate

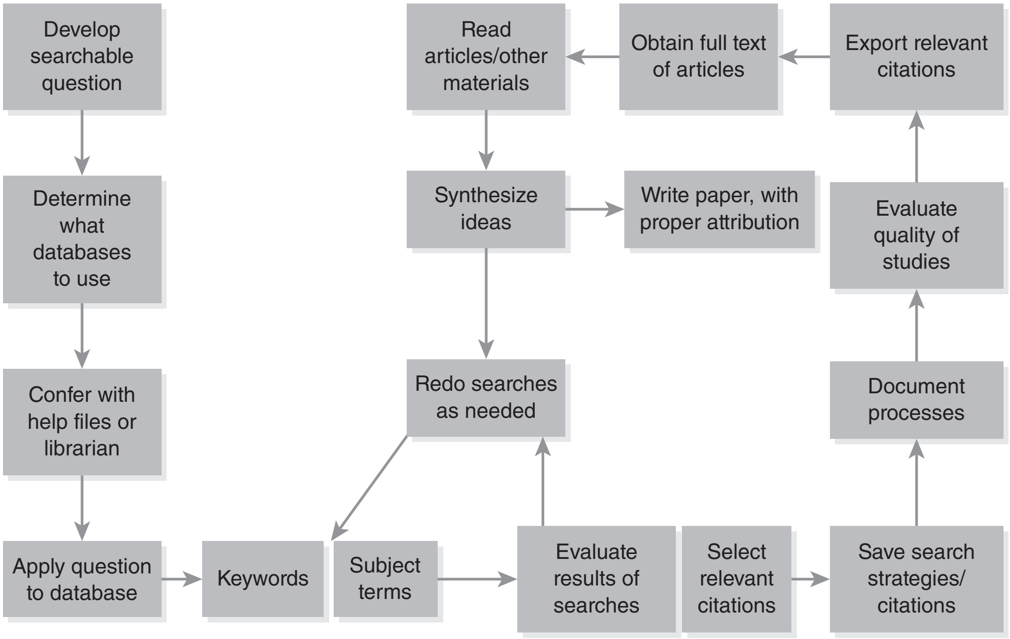

Develop searchable question
Determine what databases to use
Confer with help files or librarian
Apply question to database
Keywords
Subject terms
Evaluate results of searches
Select relevant citations
Save search strategies/ citations
Document processes
Evaluate quality of studies
Export relevant citations
Obtain full text of articles
Read articles/other materials
Synthesize ideas
Write paper, with proper attribution
Redo searches as needed

FIGURE 15.2 Using the medical literature to provide optimal patient care.

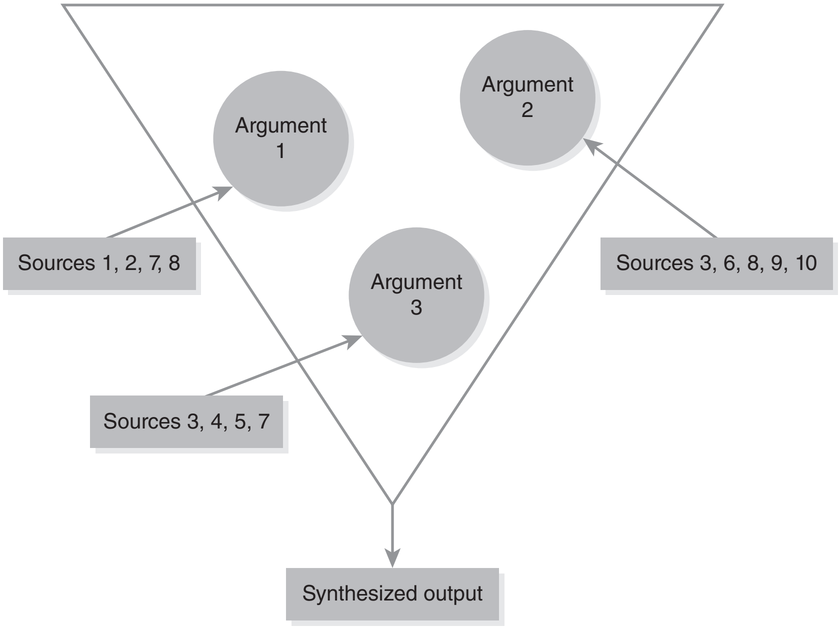

Argument 1
Argument 2
Argument 3
Sources 1, 2, 7, 8
Sources 3, 6, 8, 9, 10
Sources 3, 4, 5, 7
Synthesized output

FIGURE 15.3 A more in-depth look at the ask, acquire, and appraise steps in the EBP process.

the sources themselves. It offers transparency to others in your scholarly discipline inviting them into your thought process and establishing your credibility related to the topic.

Citation Styles, with a Focus on AMA and APA

The citation style that needs to be used for a particular project depends on the discipline in which one is writing and sometimes on the particular instructor or publisher guidelines or institutional department. Medicine as a discipline commonly, but not always, utilizes the American Medical Association (AMA) style.[5] The most current version of this style, as of the writing of this book, is AMA 10th edition. This is considered the same format as JAMA (*Journal of the American Medical Association*). Writers in the nursing discipline frequently utilize the American Psychological Association (APA) style.[6] The most current version of this style, at the time of publication of this book, is APA 6th edition. The APA style is commonly used in social and behavioral sciences, especially when the research is qualitative. Researchers in public health, health policy, or health promotion, tend to use APA style. Areas of public health with a focus on epidemiology and biostatistics tend to use AMA/JAMA style as their work crosses over into clinical medicine. Most health professionals should be familiar with either APA or AMA style, or both, to contribute to the scholarly conversation within the health sciences.

When writing for a more formal project such as a thesis or dissertation, a journal submission, or a grant proposal, follow whatever citation style requirements are put forth by the governing body asking for the finished work. If no citation style is specified in guiding instructions, inquire with the thesis or dissertation advisor, journal editor, or granting agency as appropriate. Some publications may publish their own style manuals with additional requirements. These requirements can be found in the "Information for Authors" or "Instructions to Authors" guidelines usually provided on the publisher's website. Additional guidance may be available for further information within specific disciplines; for instance, the National Library of Medicine (NLM) has an entire online guidebook on citing in medicine that goes beyond the formatting information available in the AMA Manual.[7] Whatever citation style is chosen, be consistent with the proper use of that style and remember the overarching purpose of providing citations: to be transparent in one's work and invite others to examine and respond to your work as part of the scholarly conversation you have entered.

Each of these styles has unique features. The differences that exist in reference styles relate to how the various details (e.g., author's name, etc.) are formatted or which elements are used. For example, APA uses an alphabetically organized reference list, whereas AMA uses a numerically sequential reference list. There are additional variations in utilization of punctuation, formatting, and other specifics between styles. Although there are subtle differences in the details of the ways different citation styles order elements and rules for writing, generally papers are double-spaced with references being single-spaced. The following examples illustrate the differences among these styles. These sample citations show a book by more than one author and a journal article by more than one author.

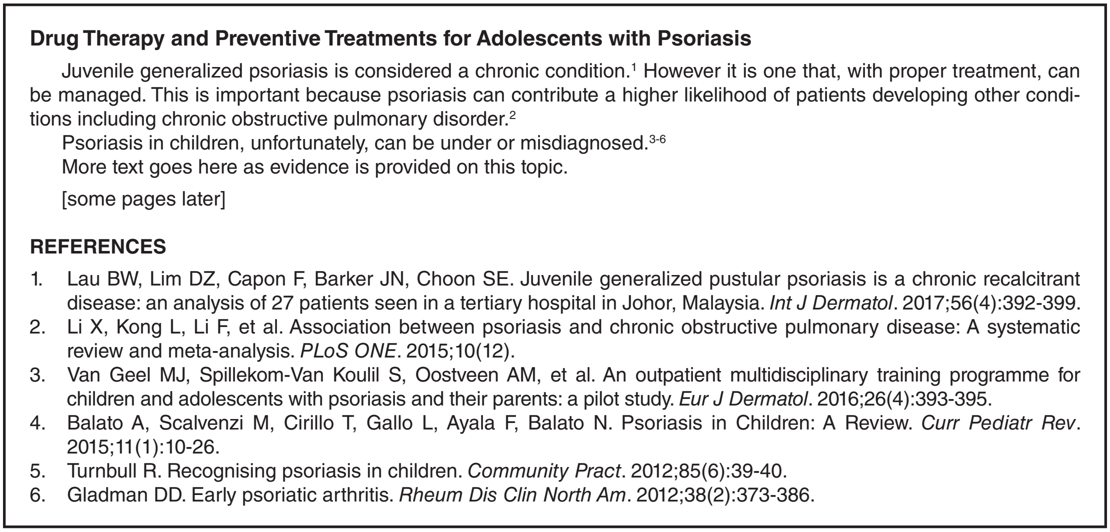
AMA

1. Hooker RS, Cawley JF, Everett C. *Physician Assistants: Policy and Practice.* 4th ed. Philadelphia, PA: F. A. Davis; 2017.
2. Bloomer RJ, Falvo MJ, Schilling BK, Smith WA. Prior exercise and antioxidant supplementation: Effect on oxidative stress and muscle injury. *J Int Soc Sports Nutr.* 2007;4:9–19.

APA

Hooker, R. S., Cawley, J. F., & Everett, C. (2017). *Physician assistants: Policy and practice* (4th ed.). Philadelphia, PA: F. A. Davis.

Bloomer, R. J., Falvo, M. J., Schilling, B. K., & Smith, W. A. (2007). Prior exercise and antioxidant supplementation: Effect on



Drug Therapy and Preventive Treatments for Adolescents with Psoriasis

Juvenile generalized psoriasis is considered a chronic condition.[1] However it is one that, with proper treatment, can be managed. This is important because psoriasis can contribute a higher likelihood of patients developing other conditions including chronic obstructive pulmonary disorder.[2]

Psoriasis in children, unfortunately, can be under or misdiagnosed.[3-6]

More text goes here as evidence is provided on this topic.

[some pages later]

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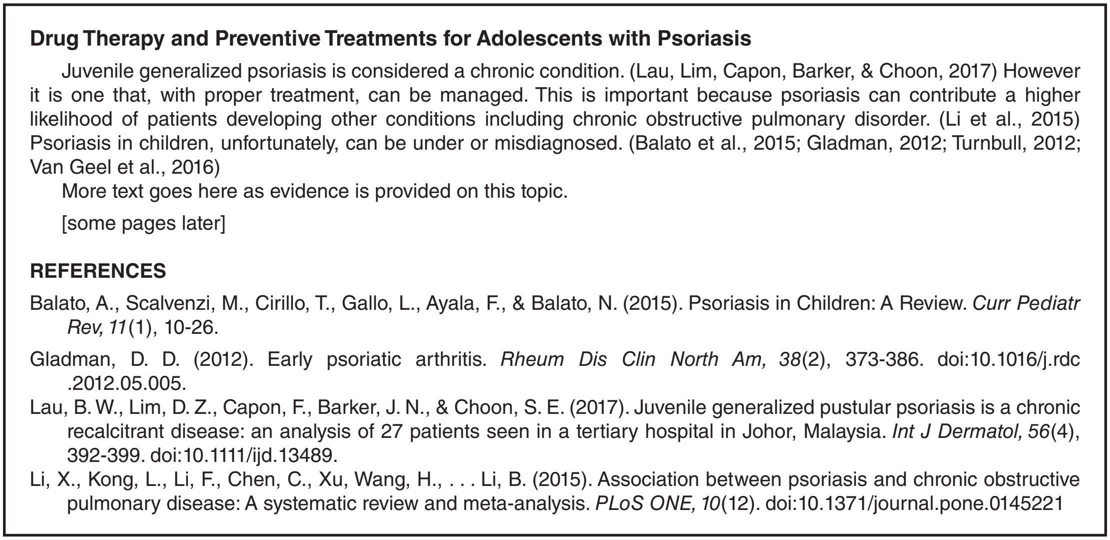
5. Turnbull R. Recognising psoriasis in children. *Community Pract*. 2012;85(6):39-40.
6. Gladman DD. Early psoriatic arthritis. *Rheum Dis Clin North Am*. 2012;38(2):373-386.

FIGURE 15.4 AMA style.

oxidative stress and muscle injury. *Journal of the International Society of Sports Nutrition, 4*, 9–19. doi:10.1186/1550-2783-4-9.

AMA citation style uses numbering within the text (as superscript numbers at the end of sentences). The endnotes in the references list at the end are, unlike APA style, not in alphabetical order, but in the order they appear in the text (**FIGURE 15.4**). APA citation style uses inline citations within the text and endnotes at the end in the form of a reference list that is in alphabetical order of the last name of the first author (**FIGURE 15.5**). Other styles utilize other conventions for how the inline citations and endnotes are done, or utilize footnotes at the bottom of each page instead of endnotes.



Drug Therapy and Preventive Treatments for Adolescents with Psoriasis

Juvenile generalized psoriasis is considered a chronic condition. (Lau, Lim, Capon, Barker, & Choon, 2017) However it is one that, with proper treatment, can be managed. This is important because psoriasis can contribute a higher likelihood of patients developing other conditions including chronic obstructive pulmonary disorder. (Li et al., 2015) Psoriasis in children, unfortunately, can be under or misdiagnosed. (Balato et al., 2015; Gladman, 2012; Turnbull, 2012; Van Geel et al., 2016)

More text goes here as evidence is provided on this topic.

[some pages later]

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FIGURE 15.5 APA style.

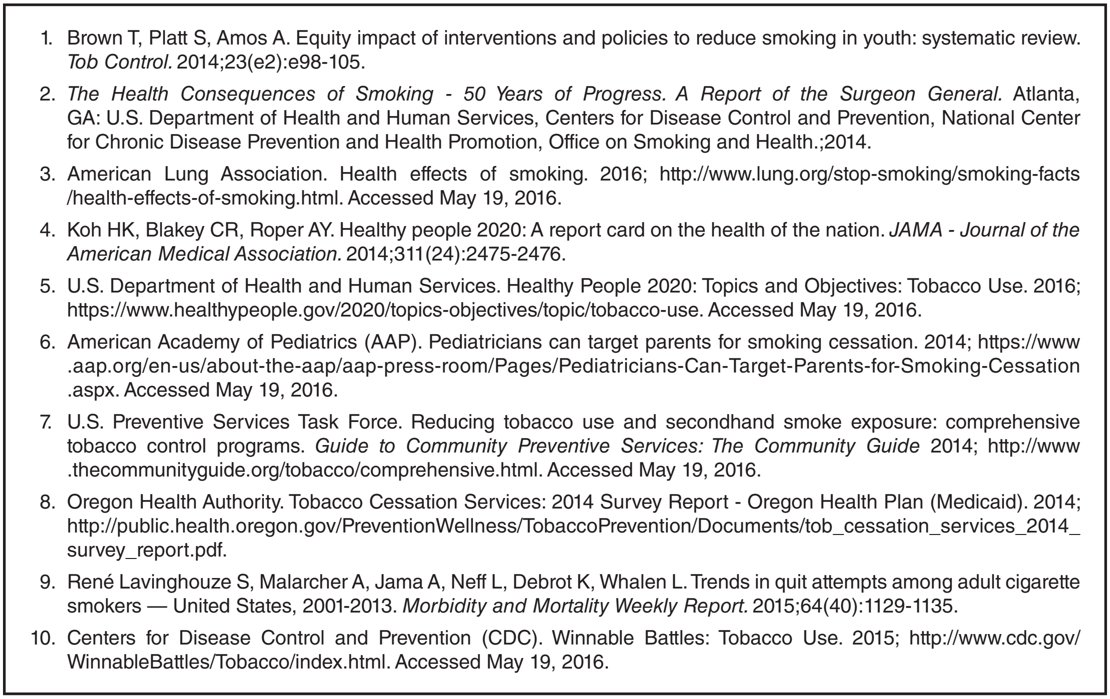
Cite Everything

Scholarly articles published in peer-reviewed journals are not the only type of resource that should be cited. Any resource, whether a conversation with an expert in the field, a website, a data set, a newspaper article, a government agency report or an association policy statement, should be cited. All these different types of resources have slightly different elements that should be included in the formation of a proper citation for them: for instance, a website needs always to have both a web address and the most recent access date (by the researcher) of that web address.

Examples of bibliographies in both AMA and APA styles that provide an idea of what it looks like to cite all types of resource types can be seen in **FIGURES 15.6** and **15.7**. Depending on the citation management tool utilized and the fact that many non-journal articles must be entered by hand (as opposed to being exported from a journal database) sometimes makes dealing with non-journal resource types in citations more challenging. Despite this, however, these are important sources that must be reflected in the researcher's thought processes and attributed like journal articles.

Bibliographic Citation Management Tools: "Where the Magic Happens"

Current bibliographic citation management tools facilitate the ease of organizing citations and including them in a manuscript. However, these tools do not replace the need for individuals to review the output of the tool for accuracy. Although tools exist that can automate the process of formatting citations, computer programs sometimes make errors, so all output from such a program should still be reviewed by human eyes prior



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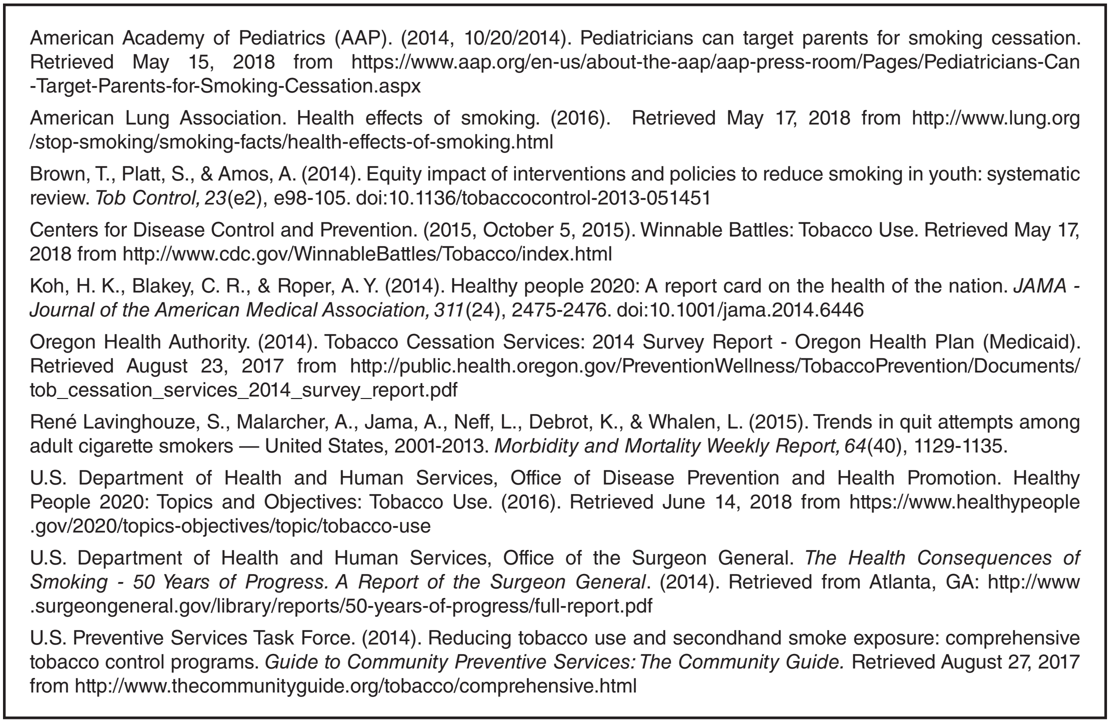
10. Centers for Disease Control and Prevention (CDC). Winnable Battles: Tobacco Use. 2015; http://www.cdc.gov/WinnableBattles/Tobacco/index.html. Accessed May 19, 2016.

FIGURE 15.6 Example of bibliography showing multiple types of resources in AMA style.



American Academy of Pediatrics (AAP). (2014, 10/20/2014). Pediatricians can target parents for smoking cessation. Retrieved May 15, 2018 from https://www.aap.org/en-us/about-the-aap/aap-press-room/Pages/Pediatricians-Can-Target-Parents-for-Smoking-Cessation.aspx

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U.S. Department of Health and Human Services, Office of the Surgeon General. *The Health Consequences of Smoking - 50 Years of Progress. A Report of the Surgeon General*. (2014). Retrieved from Atlanta, GA: http://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf

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FIGURE 15.7 Example of bibliography showing multiple types of resources in APA style.

to submission to the journal publisher, course professor, or another recipient of the material.

It is useful to reference the appropriate guide to familiarize oneself with a citation style in order to adequately review the output from an automated tool. Academic and public libraries will typically have copies, sometimes both physical and electronic, of APA and other major citation styles available in their collection that can be used to check if the style is being properly followed. Additionally, other excellent online resources for reference, such as the Purdue Online Writing Lab (OWL) exist, although the citation styles within the OWL are focused only on APA and MLA citation styles.[8] Ultimately if a researcher is going to be writing in a particular citation style on a regular basis, it behooves the researcher to purchase their own copy of a guide covering the citation style they use most frequently.

Ideally, a researcher already has a bibliographic citation management tool in place and is familiar with how to use it prior to starting the literature research process in-depth. As they start the process, engaging in the ASK, ACQUIRE, and APPRAISE steps in the evidence-based practice cycle, they can use this tool to collect relevant citations gathered from database searches. This makes it easier to track on the reference materials for different parts of an argument or issue. Such tools usually include a feature to organize citations into different groups or folders. This feature helps track which resources need to be cited for different parts of the writing. These tools typically include a search feature. They also allow entry of new references by hand if needed. This feature is particularly useful for citing resources such as websites that do not have an automated mechanism for exporting citation information. Later, when it is time to write the paper, these tools interact with Word or other text software to allow citations to be placed into the paper at appropriate places in the chosen citation style.

Many bibliographic citation management tools exist. If you have less than 10 citations or do not intend to use those citations again, almost any tool will work. However, if you have more than 10 citations or plan to refer back to that body of citations a more robust tool is needed. Some, like Zotero®, EasyBib®, BibMe®, and others are freely available. Others such as Mendeley®, RefWorks®, or EndNote® are available for purchase or may be available for free to an institution's faculty, staff, and students through a license purchased through the institution's library. Upon leaving that institution access to this institutional version of the tool will end so graduates would need to purchase their own version of the tool at that time.

Listings of the free and for-purchase bibliographic citation management tools can be found online. Check with your institution's library first to see if there is a tool you can freely use via your organization. There is no one "best" tool between the products available. Most of the programs should be able to handle certain functions like importing citations from databases, finding and deleting duplicate records, ability to format in and switch between multiple citation styles, and ability to bring in citations from your citations library into the document in which you are writing.[9]

Copyright, Fair Use, and Avoiding Unintentional Plagiarism

U.S. copyright law, contained in Title 17 of the United States Code is founded on the idea that the formation of new ideas will flourish and be more likely to be disseminated when the creators of these ideas have protection and attribution for them.[10] When a work is fixed in a tangible medium of expression (such as, but not limited to, a written document, videotaped performance, and more) copyright applies to that work, even if the author of it has not applied for specific protections for it. This means that the author of the work, unless they indicate otherwise through a flexible license like those available through Creative Commons, has the exclusive right to reproduce, modify, and distribute their material and may prohibit others from doing so.[11]

Some modifications to copyright include the concept of Fair Use and the TEACH Act of 1992. Fair Use allows for the unlicensed use of copyrighted material under Section 107 of Title 17 in certain circumstances.[12] In order to qualify for use under Fair Use principles, four factors need to be considered: (1) The purpose and character of the work (commercial or non-commercial/educational use); (2) the nature of the work (factual and/or published work versus creative and/or unpublished work); (3) the amount of the copyrighted work used (a very small percentage or half the book); and (4) the effect of the use of the copyrighted work on the potential market or value of the copyrighted work.[12]

There are a number of sites online that contain checklists one can reference with more in-depth explanations of these four points.[13-14] Another modification to Title 17 and U.S. copyright law includes the TEACH (Technology, Education, and Copyright Harmonization) Act, enacted in 2002. This modification to copyright law permits the use of copyrighted works in distance education programs for non-profit, accredited educational institutions.[15-16]

Creative Commons Licensing was not part of modifications to Title 17, but that has an impact in the realm of attribution, citation, and the scholarly conversation.[17-18] Creative Commons Licenses are a way for the author of a work to designate in which ways they will permit their work to be shared, attributed, used, or modified in ways that are somewhat more flexible than traditional copyright. A Creative Commons License has four dimensions: Attribution (whether or not you will allow people to use with or without credit), ShareAlike (how or whether you will allow others to copy, modify, and distribute your work), Non-Commercial (people have to obtain your permission to use your work for commercial purposes), and NoDerivatives (whether or not you allow people to distribute only original copies and not modified copies of your work). More in-depth information about Creative Commons Licensing is available on their site (https://creativecommons.org/).

Not all materials fall under copyright law. For instance, documents of a factual nature (such as a phone directory) are not copyrighted and thus fall into what is considered the public domain. Public domain materials may be used, modified, and distributed in ways that copyrighted materials cannot, but even so should still be cited properly when they are used. Several excellent online tutorials, including the Copyright Crash Course (http://guides.lib.utexas.edu/copyright) constructed by the University of Texas, can help guide you to a better understanding on these issues.[19] Additionally, contact the librarians at your institution to consult with them on questions you may have on Fair Use, the TEACH Act, Creative Commons, public domain, or other copyright issues.

Even when someone is aware that all of these frameworks exist and that blatantly using someone words as one's own without attribution is wrong, unintentional plagiarism still happens. Unintentional plagiarism can occur when an individual is lifting words from various resources and has not synthesized them and made those ideas their own but instead leans on the use of the wording from the consulted sources overly much. Just rearranging a few words in the sentences by the original author does not make it your own, nor does quotation marks around some sentences while citing the author. True and proper attribution can only occur through the process of synthesis, where the researcher incorporates referenced works into their thinking and combines them with their own ideas to create something new. Sometimes, a cited author's wording is better than anything a researcher thinks she could write. When this occurs, it is better to properly quote and cite the smallest core possible of that essential wording than to lift entire paragraphs and to put quotes around them. Taking the time to cite and attribute properly is not just a courtesy to the cited authors, but reflects a shared level and understanding of scholarship and professionalism. The process increases your credibility as an author.

Summary

Utilizing the appropriate citation style properly and consistently for any work created is a core standard within all fields in academia and research. Doing so not only provides the attribution due to the original authors of the resources consulted during the research process but invites others to participate in a dialogue with the author, who themselves are now part of the scholarly conversation on this topic. Transparent documentation of the resources utilized to make one's arguments and come to particular conclusions only serves to strengthen one's credibility and arguments within the work. Existing technical formatting tools will evolve, but the researcher must still understand the larger philosophical purpose of the process. Researchers who take the time to learn these bibliographic citation tools will receive continued benefits in the log run.

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CHAPTER 16

Writing and Publishing in the Health Professions

James F. Cawley, MPH, PA-C, DHL (Hon.)

CHAPTER OVERVIEW

As clinicians and teachers, being a healthcare professional brings a sense of obligation to contribute to the existing body of research knowledge. This obligation applies to clinical practitioners, students, and faculty in a wide range of healthcare disciplines. The development of skills in writing, formal presentation, and publishing is essential for healthcare professionals as they progress through and develop their careers. Such skills facilitate the expansion of multiple career options and further existing knowledge within the professions.

Skills and techniques related to research methods, report writing, and publishing should be part of the educational preparation of all healthcare professionals. Scholarly work is increasingly a requirement for graduation in the healthcare professions. In this chapter, the essential components of a research paper are reviewed in general, and the process of writing research papers generated by the various health professions is addressed. Presentations and posters are discussed.

LEARNING OBJECTIVES

- Identify different style manuals.
- List and discuss the processes of publication.
- Describe how to get published.
- Outline and define the elements of a manuscript.
- Define *peer review, blinded review, authorship*, and *order of authors*.

The process by which research papers are transformed into research publications in the biomedical literature is also discussed. The expansion of clinical investigations and the involvement of more practicing clinicians in the research process requires practitioners to develop publication and presentation skills.

Introduction

Since the 1600s, thinking and writing have been classified into two types: literary and scientific. The literary style has been associated with fiction, rhetoric, and subjectivity, whereas the scientific style has been steeped in fact, plain language, and objectivity. Through the centuries, this division of style increased as the body of scientific knowledge grew; barbs were increasingly exchanged between the two camps of thinkers and writers. By the mid-1800s literature and science often stood as two distinct domains, particularly in their respective written work. Although dissension and distance remain between these two broad fields, numerous examples of crossovers have shed light on scientific truths drawing from both domains. During the twentieth and twenty-first centuries, medical thinking and writing and the expression of medical knowledge have been reflected in the evolution of scientific writing.

Every healthcare professional and student should be able to communicate through writing. Effective writing in general and writing for publication are skills to be learned. Scientific writing has its styles and processes. Generally, short, effective sentences with a subject and predicate are better than long, multiple comma sentences. Learn to write clear and strong declarative statements in an active voice.

Style Manuals

Many resources are available that facilitate the process of preparing research for acceptance as an education capstone and publication. **TABLE 16.1** represents a variety of resources that can enhance this process.

Before selecting a particular style manual as a guide, review the journals that offer publishing opportunities pertinent to the research field. The style requirements of the publishing resource

TABLE 16.1 A Step-by-Step Approach to Publishing Your Manuscript

The essential steps in the process of publishing a paper in the biomedical literature are as follows:

1. Determine the central message of the paper.
2. Decide if the paper is worth writing.
3. Identify the appropriate audience for the paper.
4. Select the journal for which you will prepare the paper.
5. Search the literature.
6. Determine authorship and an expected timetable.
7. Assemble the sources and materials needed to write the paper.
8. Develop a structure for the paper; make a detailed outline.
9. Write the first draft conforming it the journal's requirements for manuscripts.
10. Revise the first draft and cycle through several more drafts; add appropriate tables, graphs, and illustrations.
11. Finalize the manuscript; complete all sections.
12. Obtain comments and critiques from selected "personal consultants."
13. Submit the article to the selected journal in the required format; include a formal cover letter with the appropriate disclaimer.
14. Promptly respond and revise the manuscript as indicated in the editor's communication; respond to all authors' queries.
15. Resubmit the corrected manuscript; proof the final typescript; assign copyright.

(journals or books) must be followed stringently. For most peer-reviewed biomedical publications, two distinct resources contain the most frequently required formatting and guideline protocols. These are the American Medical Association Manual of Style[1] and the Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals (formerly known as the Uniform Requirements for Manuscripts Submitted to Biomedical Journals), created by the International Committee of Medical Journal Editors.[2]

The *AMA Manual of Style* includes five sections of in-depth instruction on topics including preparing an article for publication, style, terminology, measurement and quantitation, and technical detail. The International Committee of Medical Journal Editors' online documents describe in depth a range of ethical considerations, publishing and editorial issues, manuscript preparation, and reference formatting and usage guidelines. Together, these two resources offer the most commonly used guidelines and requirements for publishing in the peer-reviewed biomedical literature. However, it is always important to consult the "Instructions to Authors" (sometimes referred to as "Information for Authors") section of any publisher to whom a manuscript is submitted because they may include other resources, and preferences vary from journal to journal. There is no substitute for consulting the "Instructions for Authors," which is published by all journals. It is the author's responsibility to submit manuscripts in the required style of target journals. Failure to follow the prescribed style is likely to result in rejection of the manuscript.

The gold standard of style guidelines in the biomedical field is put forth by the International Committee of Medical Journal Editors (ICMJE). The ICMJE has produced multiple editions of what was once known as the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals* (URM), revised and renamed *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals* (ICMJE Recommendations) in 2017.[2] The URM was first published in 1978 as a way of standardizing manuscript format and preparation across journals. Over the years, issues in publishing that went well beyond manuscript preparation arose, resulting in the inclusion of sections on editorial policy.

Writing

All students in healthcare professions should know how to structure a research paper and how to modify it into a publishable article. There are differences between a thesis or dissertation and a published paper. The skills needed to write for publication are also important to the seasoned clinician who has observed an interesting clinical case and seeks to contribute to the literature by "writing it up" for publication.

The proper culmination of any scientific research effort in a formal educational setting is the production of a written document reflecting the work that was completed. Recording one's work in a formal style has been and remains the hallmark of scholarly activities.

Scientific papers are the vital currency of academic endeavors and knowledge dissemination. The quality and timeliness of information and its presentation in scholarly papers are determinants of major decision points in central collegiate activities:

1. assignment of student grades;
2. student advancement and graduation;
3. faculty appointment and advancement;
4. tenure decisions;
5. perceptions of professional leadership;
6. and, national academic reputations.

Publishing in prestigious journals with regularity is the expected and rewarded activity in most academic healthcare centers. However, of all the faculty teaching in U.S. colleges and universities, only a small proportion publish regularly.

A healthcare profession's vitality, relevance, and intellectual pedigree are reflected in its literature.[3] When judged by that standard, some of the health professions may be viewed as underachieving. Many believe there is a critical and ongoing need for the healthcare professions to improve contributions to both the general biomedical literature and a specific healthcare profession's literature. One way to obtain this goal is to foster student research and to write with the hope (and aim) of those skills carrying forward into clinical practice.

For faculty members and students of healthcare professions, writing ability and familiarity with publishing in the realm of healthcare science are essential professional skills. These skills, which are critical for success, can be learned by students, perfected by faculty, and appreciated by readers, both professional and lay. Beyond the academic setting, this process can pose a challenge for health professionals. **BOX 16.1** provides a list of facts and myths about medical writing that are helpful to the clinician interested in research. Diana Hacker and Barbara Fister have composed a helpful website that includes examples of papers written in four commonly referenced style manual formats (http://www.dianahacker.com/resdoc/). Additionally, many style manuals now have quick reference links on the Internet; California State University of Los Angeles offers a useful site as a point of departure (http://calstatela.libguides.com/style).

BOX 16.1 Medical Writing Facts and Myths

Myth: "I'm a care provider, not a writer."
Fact: Writing is not a career but a necessary skill for medical professionals.
Myth: "I don't have any talent for writing. I've always been bad at it."
Fact: Writing is a skill, not a talent. Medical professionals should learn to write effectively.
Myth: "Writing has nothing to do with science."
Fact: Effective medical writing requires the same qualities found in scientific thought: logic, clarity, organization, and precision.
Myth: "If a piece of writing gets published, it's a good piece of writing."
Fact: Many published medical papers are badly written.
Myth: "Until I have my ideas clearly organized in my head, I shouldn't start writing."
Fact: The best way to clarify thinking is to start writing. Research shows that the act of writing helps clarify and organize thinking and generate ideas.
Myth: "I'll never be eligible for promotion or tenure unless I get a terminal degree. Why should I bother publishing if it won't help my career?"
Fact: Publishing papers in respected peer-reviewed journals has substantial academic value and generates far more career-enhancing opportunities than having a terminal degree and not publishing.

Data from St. James D. Writing and speaking for excellence: A brief guide for the medical professional. Boston, MA: Jones & Bartlett; 1997:13.

Research Papers

In the healthcare field, as in most other fields, good scientific research papers are the most common form of expression of a scientific finding. Research papers have a clear, well-defined structure. The logical sequence of the research paper's sections (i.e., Introduction or Problem, Review of Literature, Methods, Results, and Discussion) is accepted as the gold standard of the classic research paper structure. This format requires the author(s) to address a given topic answering four basic questions:

1. What is the issue?
2. What methods have been used to investigate the issue?
3. What was found?
4. What are the implications of the findings?

Research papers take several forms, but generally, the best form begins by posing a question or identifying a problem. The question may address the need for further research on an issue, propose a new hypothesis, or justify further analysis. The conventional format and approach used in research papers are derived from what Huth calls the concept of critical argument.[4] This idea holds that research papers must convey information in such a way that the reader is convinced the research paper's findings are well considered and ultimately valid.

Critical argument describes text that is coherent and consists of a series of reasons, statements, or facts intended to support or establish a point of view. This tone is "critical" in the sense that it carefully scrutinizes the source of the text's assertions. The "critical argument" is the heart of research writing.

Policy Papers

There are also papers that employ research that pertain to policy and politics, business, and technical fields. Such papers are often termed "white papers." In the world of policy, white papers guide decision makers with expert opinions, pointed recommendations, and analytical research. A similar type of paper is the briefing paper, which typically provides a well-researched overview of an issue or problem with targeted analysis and recommendations. Briefing books and white papers give decision makers a background of an issue and then gives a deep analysis that supports the core findings and/or recommendations.

Prose Revision

Research articles published in the biomedical literature typically present new and original information on topics relevant to the primary readership. The accepted scientific standard is that the investigators have applied reasonable standards of methodological rigor and have presented their findings in an accurate, concise, and clearly stated fashion. An extensive review and revision process is required to create an accurate, concise, and clearly stated manuscript. A reader must clearly understand the intent and purpose of a manuscript. Rarely is the first draft of a manuscript accepted for publication. After a paper has been written, it must be reviewed, revised, and reread a number of times. A first step toward the revision of a manuscript is to revise for larger segments of content, such as missing or unnecessary information, or erroneous/misplaced content or sequence. The next step is to focus on prose, including sentence length, paragraph length, clauses, phrases, modifiers, and word choices. In revising prose, a seasoned writer seeks to develop fluency. Fluent prose runs along as the reader expects it to run. The reader is not jarred by defects that interrupt the line of thought. Short, simple sentences and a simple structure are best. Once the initial revisions have been made, two people should review the manuscript. One person should be knowledgeable about the subject and scientific writing. The other person should be a general reader. Suggestions gleaned from these reviewers can be used to revise the manuscript again.

Reference Lists

Proper citation of sources of information used in a paper as references is critical. Two reference citation styles are commonly used in academic and biomedical circles. The Vancouver style is a distinctive academic reference citation method where the author(s) and year of publication are cited in the text as they are used. At the end of the paper, these references are listed alphabetically by the first author's last name. This format is typical for graduate school research papers.

The reference citation style used in most medical and health professions journals is the style of the *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals* as developed by the International Committee of Medical Journal Editors,[3] and formerly the Council of Biology Editors.[2] This reference format for a journal article takes the following form:

> *Author(s). Title. Journal. Year; Volume: Pages.*

Here is an example:

> *Hanson RL, Pettitt DJ, Bennett PH, et al. Familial relationships between obesity and NIDDM. Diabetes. 1995;44:418–422.*

Consistency is one of the most important aspects of reference citation in an academic paper. Reference citation style and policies are typically included in the "Instructions for Authors' section published in journals. References cited should include only those documents that are readily available. You, as the author, should have access to every reference, either electronically or in hard copy. A good dictum to remember is "If you can't put your hands on it, don't cite it."

Special formats and/or requirements exist for monographs, government publications, informal documents, Internet sources, and personal communications. Here are some additional points about references:

- Recent literature sources are now available on the Internet on PubMed.
- Textbook citations should be rare.
- Garbled, incomplete, or nonfunctional references, particularly Internet citations, will disturb your readers (and editors).
- Citations from Internet sources such as Wikipedia, WebMD, Medscape, and the like are not acceptable.
- References to subscription services (e.g., ClinicalKey, UpToDate, etc.) are not acceptable.

Authors should refrain from citing a "personal communication" unless it provides essential information not available from a public source, in which case the name of the person and date of communication should be cited in parentheses in the text, not in the references section. It is always important for authors to obtain written permission and confirmation of accuracy from the source of a personal communication.

Some, but not all, journals check the accuracy of all reference citations; thus, citation errors are not uncommon in the published version of articles. To minimize such errors, references should be verified using either an electronic bibliographic source, such as PubMed, or print copies from original sources. Authors are responsible for checking the accuracy of all references including checking sources for information about retractions. References should be numbered or listed consecutively in the order in which they are first mentioned in the text. Identify references in text, tables, and legends by Arabic numerals in parentheses. References cited only in tables or figure legends should be numbered by the sequence established by the first identification in the text of the particular table or figure. The titles of journals should be noted according to the style used for MEDLINE (http://www.ncbi.nlm.nih.gov/nlmcatalog/journals).[2]

References drawn from Internet sources for use in academic papers have created an ongoing controversy on the frontier of scientific communication. Internet sources are becoming a leading category of reference information used by authors in presenting a paper or defending a thesis. Internet sources allow authors to obtain information that should be accurate and current. For example, in a paper on the topic of healthcare professionals in surgery, an essential "factoid" included in the first paragraph of this paper might be the current number of providers working in a particular field of surgery. In the past, published information would have been consulted to obtain that information, which would be, by its very nature, dated. Presently, consulting an Internet source is more likely to yield the most current data available.

The controversy over Internet resources is to be sure of the source of information. Many Internet sites appear to be authoritarian, but they are not. Some might support products of questionable value, and some might convey individual opinions, which lack the science to support contentions. Investigators must be sure of the scientific value and trustworthiness of all sites.

Citation of Internet Sources

Many, but not all, online sources have value. Some Internet sources are unreliable and have questionable credibility. It is now common practice to include Internet references in peer-reviewed medical and healthcare literature. Internet reference sources can and should be permitted with the following ground rules:

- The Internet source is not a personal Internet site (e.g., an individual home page).
- Any person can readily access the Internet site and obtain the same information cited by the author.
- The citation contains as much specific information as possible.
- The date of access is always included.

The following examples of Internet citations are from the American Medical Association's *AMA Manual of Style: A Guide for Authors and Editors*, 10th ed.

1. Rosenthal S, Chen R, Hadler S. The safety of acellular pertussis vaccine [abstract]. *Arch Pediatr Adoles Med* [serial online].

1996;150:457–460. Available at: http://www.ama-assn.org/sci-pubs/journals/archive/ajdc/vol_150/no_5/abstract/htm. Accessed November 10, 1996.

2. Gostin LO. Drug use and HIV/AIDS [*JAMA* HIV/AIDS Web site]. June 1, 1996. Available at: http://www.ama-assn.org/special/hiv/ethics. Accessed June 26, 1997.

Additional care must be taken to ensure that information or texts acquired from Internet sources are properly acknowledged. According to Glass and Flanagin, there are four types of plagiarism:

1. *Direct plagiarism:* The Verbatim lifting of passages without enclosing the borrowed material in quotation marks and crediting the original author.
2. *Mosaic:* Borrowing the ideas and opinions from an original source and a few verbatim words or phrases without crediting the original author. In this case, the plagiarist intertwines his or her own ideas and opinions with those of the original author, creating a "confused, plagiarized mass."
3. *Paraphrase:* Restating a phrase or passage, providing the same meaning but in a different form without attribution to the original author.
4. *Insufficient acknowledgment:* Noting the original source of only part of what is borrowed or failing to cite the source material in such a way that a reader will know what is original and what is borrowed.[5]

A key rule is to provide any and all information needed to allow the reader to go to the same Internet site and review the same information cited by the author. This cardinal rule also applies to published reference sources. The second rule is completeness; follow a sequence of author(s) (individual[s] or an organization), work title, site, latest date, Web address, pages (if applicable), and any other specifics that allow the reader to access the site. If the reader is unable to verify citations in an article, doubts about the validity of your efforts may arise.

Electronic Journals

Most medical journals are now published in electronic as well as print versions, and some are published only in electronic form. Some e-journals are listed among MEDLINE titles. The principles of print and electronic publishing are identical, and the recommendations of the ICMJE apply equally to both. Electronic publishing provides opportunities for versioning and raises issues about link stability and content preservation. There are three e-journal approaches:

- Journals that are completely electronic with no regular print version;
- Journals that are titled the same in both the print and electronic versions, but each publishes some unique content;
- Journals with both print and electronic versions that publish the same content.

Approaches to Publication

A potential writer, such as a new graduate from a healthcare profession program, an experienced clinician, or a faculty member, may take a wide range of approaches toward entering the world of the published. For many clinicians, the first effort at publication may be somewhat easier and have a greater chance at success if a manuscript other than an original research article is submitted. As publication efforts progress, the alternative options may be considered. Beginning with something other than an original research manuscript offers a new author experience in dealing with journals, editors, and the review process. A good place to start is sending query letters to the publishing editors of journals you wish to consider as potential targets.

A query letter is an appropriate method for determining interest in a research paper, a commentary, or an opinion article among biomedical editors. Responses to a one-page query letter can be used to gauge the interest of a particular journal in publishing an article on a certain topic.

Addressed to the editors of one or more potential target journals, a query letter should pique the editor's interest by asking, "Would you consider a submission on [your topic here]?" Avoid forcing the editor to make an immediate decision; recognize that no editor will commit to a publication decision before seeing the final manuscript and obtaining at least one other review. If they are not interested in your topic, you and the journal can save a lot of time and effort by establishing this up front. Query letters should be sent to a number of target journals. However, the manuscript should be submitted to only one journal at a time. If the manuscript is turned down for publication, it can be submitted to another journal.

Best Choices for New Writers

To become familiar with the process of manuscript submission and peer review, it may help to start small and consider beginning with case reports, review articles, book reviews, or letters to the editor. They are listed in the descending order of their perceived value and importance in peer-reviewed publications, but all are good starting points for less-experienced writers. Each of the categories has different content and requirements, but the rigor of preparation is typically less than that required for an original research article. These options are described in more detail in the following sections. On the opposite end of the spectrum, editorials, book chapter authorship, and textbook editor roles are typically reserved for subject matter experts and invited senior academicians.

Original Articles

Regarding academic currency, original articles are typically valued more highly according to the importance of their content, their relevance for promotion and tenure of the author, and establishing the author's professional reputation. Original articles are not required to be data-driven clinical projects of "bench science" or laboratory origin. They may instead reflect policy analysis, utilization patterns, cost-benefit analyses, and a host of other relevant topics that contribute to advancing the knowledge base of the healthcare professions. The key is they are original pieces of work that represent an original investigation or approach.

Clinical Review Articles

The clinical review is one of the most common types of papers that appear in healthcare literature. This reflects, in large part, the need for practicing clinicians to obtain an easy-to-read, concise summary of a particular health condition or disease. Review articles cite current theory and clinical practice for specific diseases and conditions, but they do not consist of original research on the disease or condition conducted by the author(s). Typical section headings of a clinical review article include Introduction, Etiology, Pathophysiology, Clinical Manifestations, Diagnostic Imaging/Laboratory Findings, Diagnosis, Treatment, Prognosis, Health Promotion/Disease Prevention, and Recommendations.[6]

Systematic Reviews

A more sophisticated clinical review format is the systematic review, in which a far-reaching survey of the existing literature on a given topic is performed, analyzed, and presented. Systematic reviews essentially comprise a detailed literature review of all retrievable studies on a given topic; they attempt to identify, appraise, select, and synthesize all available high-quality research evidence relevant to that question. Systematic reviews often use statistical methods (meta-analyses) to combine results of the eligible studies, or they may score the levels of evidence depending on the methodology used when they pool similar data from a number of studies. Systematic reviews are more extensive and transparent than traditional literature reviews and depend heavily on current bibliographic retrieval services (e.g., PubMed) as critical sources.

Case Reports

Case reports, once a staple of clinical literature, and for that matter, the format of many academic teaching exercises and presentations, remain an important type of paper appearing in biomedical journals.[2] Case reports are typically detailed, illustrated clinical descriptions of individual occurrences of disease. Over the past 20 years, however, case reports have become less frequent in the biomedical literature and tend to convey little new information. Biomedical journals usually publish clinical research trials, but case reports may provide important information. Those that merit publication include case histories that are unique, or nearly unique and cases of a new disease or an unexpected association (such as an outlier case or one with unexpected therapeutic events). They may represent notable early clinical observations that herald new diseases. Case studies still appear in the healthcare literature and offer practicing clinicians an opportunity to share interesting and informative cases.

Editorials

The editorial section of journals is often the most revealing and, occasionally, the most controversial section of the journal. At times, an editorial in a major biomedical journal is an invited comment on a paper appearing in the same issue. Editors may choose to invite subject experts to compare and contrast their opinions with the paper and other related studies. Articles that have the potential for substantial impact on a disease or society are often complemented with an invited editorial, as are articles that endorse a significant departure from the traditional method of treating a disease or condition. Editorials can be personal opinion pieces that address issues and controversy in society, medicine, and the profession. Editorials sometimes present minority opinions on professional trends and directions. Editorials can be submitted by anyone, but journals may have policies that govern what can be addressed in an editorial. Generally, the editor of the journal decides on whether to publish an editorial.

Position Papers: A Variant of the Editorial

Many highly respected journals are owned by professional societies, and these often contain official statements and position papers produced by the organization. Some journals choose to publish occasional "point-counterpoint" position papers on controversial topics. Although such articles typically do not contribute new data to an issue, the questions they pose often result in the development of new studies or new ways to approach an ill-defined issue. Position papers may attempt to influence readers, members, or those outside of the profession or professional society.

Position papers sometimes deal with therapeutic or clinical issues. They are usually the result of reviews by experts who then recommend a course of action. It is common for standards of care to emerge from such positions or expert opinion.

Book Reviews

Book reviews are common departmental features of biomedical journals. In some journals, particularly those in the field of the history of medicine, book reviews comprise a large portion of the content. An effective and engaging book review begins when the reviewer, an individual well versed in the field, asks the following questions: Is this book needed? Does it add a new perspective to the topic? Is it a helpful addition to the clinician's library? Reviews of books are commissioned by the editor or the department editor and are thus usually invited publications. Book reviews may or may not count as "significant publications" by institutional promotion and tenure committees. However, doing a book review is a valid publishing opportunity and a good exercise for aspiring researchers and authors.

Letters to the Editor

For readers, the well-written, informed, pointed response to a previously appearing article can be among the most interesting sections of a journal. Letters to the editor often include frank challenges to published findings. The real and personal risk of publishing any work in a peer-reviewed journal is that writers open themselves to public and professional criticism and occasional humiliation when their work is challenged or refuted by experts on the topic. For other writers and aspiring authors, however, a letter to the editor may represent an entry channel to publication and further contributions. If they appear in a major medical journal, letters to the editor count as a "major publication" as indexed in Index Medicus. Letters to the editor should directly address a recently published paper and/or provide new information. Letters are usually limited to 500 words or fewer, and journals typically restrict the number of times letters to the editor by a given author can be published. Typically, if a published work is challenged or commented upon in some way, the original author is allowed a counter-response.

Abstracts and Posters

Abstracts and poster presentations are excellent opportunities to present research in a peer-reviewed forum. National meetings of healthcare professional organizations typically offer an excellent opportunity for poster and abstract presentations. The American Academy of Physician Assistants (AAPA) is a helpful resource, for example, and offers guidelines, which are included in the following section (used by permission).

Frequently Asked Questions

Q. What is a poster?

A. A poster is a method commonly used to present research in the biomedical sciences; it is a bulletin board that displays one or several large pieces of paper. A poster provides an opportunity to publish a very short article and discuss it with your peers at a conference. It is a static, visual medium used to communicate ideas and messages. When research is presented on a poster, the content of the poster should be focused on generating active discussion of the research. A great poster is readable, legible, well organized, and succinct. The Science and Engineering Library at University at Buffalo, The State University of New York has excellent web resources to help you create an effective poster (http://libweb.lib.buffalo.edu/guide/guide.asp?ID=155).

Q. Does it have to be original research?

A. No, although original research is the sine qua non for poster presentations, other types of research or scholarly activity are welcome. Appropriate research results from a survey, an interventional study, a secondary data analysis, an epidemiologic study, a cost–benefit analysis, an evaluation of a diagnostic test, or something else. Interesting case studies, patient vignettes, and innovative practice techniques are also welcomed. Posters that have been presented at other professional meetings within the past 12 months are typically eligible for submission. Students are strongly encouraged to present research done in the program. Faculty members are encouraged to present their educational research, innovative curricular designs, or case studies.

Q. Is the process competitive?

A. There is no competition to get your abstracts approved per se. In most cases, if the guidelines are followed, and quality work is presented, the abstract is accepted. In general, originality of the work, adequacy of the data, and clarity of expression are the determining factors for selection. Specific selection criteria vary for each category as listed below.

- Original research
    - Is the purpose or the objective clearly stated? Is the scope of the topic too broad or too narrow?
    - Is the description of the materials and methods understandable? Are the data collection and experimental techniques adequate for the study?
    - Are the analytical procedures used adequately described? Is the research design appropriate for the data collected and the subject of the study?

    - Are the results presented in sufficient detail to support the conclusions? Do they follow from the data and analysis?
    - Are the interpretations sound?
    - Is the conclusion clear?
    - Is the information presented important? Are there practical implications of the information? Is the information new? Is the research original?
- Clinical report or case study
    - Is the information presented clearly and understandably?
    - Is the information presented applicable?
    - Is the information clinically important, relevant, and significant?
- Previously presented poster
    - Is the information appropriate?
    - Does it satisfy the criteria previously given for original research?
- Educational research or interventions
    - Is the abstract thoughtful, organized, and clear?
    - Is an innovative method presented that is original and effective?
    - Are measurable outcomes presented?
    - Does the project impact special populations?
    - Does the project have value to other health professions' educators and their professions?

Q. Do you have an example of how a poster appears?

A. The University of North Carolina provides an example of the principles of poster design and summarizes the abstract review process at http://gradschool.unc.edu/student/postertips.html.

Posters

The poster display board is 8 feet wide by 4 feet tall with a 1-inch metal border. The background material is a neutral-color cloth. **FIGURE 16.1** demonstrates the look of a classic original research poster. The top banner should include the title, author names, and their affiliations. The poster should read from top left to bottom right. The title should be legible from 8 feet away and the remaining words from 4 or 5 feet away.

Look at Figure 16.1 for example. Keep in mind these important tips:

- Keep it simple.
    - Present only enough information to support your conclusions.
    - Eight poster panels are the maximum for effective presentation.
- Use graphs, charts, and figures to emphasize the key points; less text is better.
    - A good ratio is 20% text, 40% graphics, and 40% open space.
    - Don't use all capital letters; they are much harder to read.
- Above all, be clear, concise, and organized.

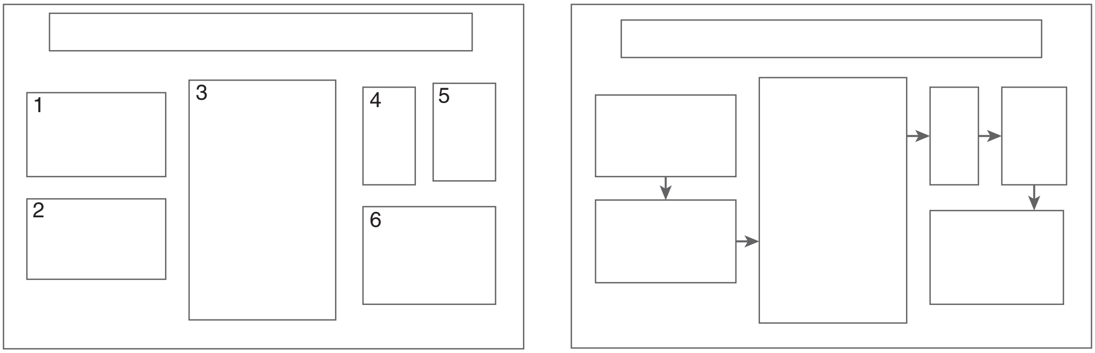

FIGURE 16.1 Example of poster formats.

Elements of the Research Paper

Tables

Tables are an essential component, the hallmark, of the Results section. As ideal vehicles for summaries of numerical and categorical data, tables are often far better than text for conveying this type of information. A table typically includes columns, rows, fields, titles, footnotes, and display trends. A table should stand alone and be readily understood without referring to the text, and each table should present at least one key result. Collectively, tables contain the vital findings of the investigation or study and represent the essence of an original research paper.

Effective tables should be constructed with a purpose in mind. Use of mutually exclusive categories is desirable, and the number of rows and columns should be kept to the minimum needed to convey the results. The use of several small tables is more effective than one large, complex table. Tables should be referred to in the text of your manuscript and placed within the text near that reference.

Illustrations and Figures

Illustrations and figures provide features central to the research paper: evidence, efficiency, and emphasis. The quality typically required for publication suggests that illustrations are best when prepared by professional graphic artists. As with tables, figures and illustrations should be referred to in the text at the appropriate point.

Titles

The title of a research study in any form is important, particularly when it is published. The title may be the reason people are attracted to your work and introduces to readers what has been published. There are two types of titles: indicative (what the paper addresses) or informative (briefly describes the paper's specific message). The title should be accurate, succinct, and effective. Clinicians must triage through a voluminous and growing number of biomedical journal articles to determine which ones should be read; the first (and usually only) part read by most readers is the title. Word selection for the title is, perhaps, one of the most critical parts of the paper because it is the principal determining factor in the reader's decision to read the paper. The title should arouse enough curiosity that the article is further examined. Creating a catchy title is an editorial art form.

In the review and/or editing process, authors should not be disappointed or defensive if the title submitted with the manuscript is changed (i.e., it is often changed substantially). Editors are experienced at determining what title best catches the readership's eye for their particular journal.

Oral Presentations

Many professional meetings provide opportunities for participants to present their research orally. A common method is a 10-minute presentation followed by a 5-minute question-and-answer session. This is an excellent opportunity to present work in progress or the results of a finished project or study. The most frequently used product for digital presentation of data is Microsoft PowerPoint. Numerous self-paced PowerPoint training courses are available from Microsoft online (http://office.microsoft.com). Additionally, entering "PowerPoint presentations" on Internet search engines results in more than a million hits on sites that offer additional instruction or assistance.

Becoming a good speaker and presenter requires experience, effort, and practice. A beginning speaker has only effort and practice at hand. The experience comes from making oral presentations. A first-time speaker or presenter can expect to be nervous. As audience size grows, so does the level of anxiety. These are normal responses and feelings; even veteran speakers get "butterflies" from time to time. Two key ways to overcome initial fears are (1) to know your material and (2) to practice, practice, and practice some more. Two common traps plague all presenters. The first is reading the visual presentation. This pitfall should be avoided carefully. If all a presenter does is read a visual presentation, there is no need for an oral presentation. There are very few audiences that cannot read. In general, use notes or keywords to guide the delivery of material. The second common mistake many first-time speakers make is they have practiced to the point of reciting a memorized piece of work. Never recite. Good speakers retain some spontaneity and emotion in their voices, and they talk to the audience. Humor can add a lot to a presentation, but it must be appropriate for the audience, the material, and the speaker.

The last key aspect of being a good speaker and presenter is to respect the time frame allowed for your presentation. Practice helps frame a time period, but it is never the same as being in front of an audience. It is better to end a presentation a bit early than to run over the allotted time. One way to avoid running over is to allow some time for questions at the end of a presentation. In some venues, directions specify the allowance of a set time period for questions. Generally, 5 minutes is a reasonable time for questions. Much depends on the length and subject matter of your presentation. A plus point for always allowing time for questions is that if you run a few minutes longer in presentation, the only thing lost is the question period. If you are short of your allowed time, it gives you a longer period to field questions.

Becoming a good presenter requires work. The more experience a presenter has, the less effort and practice necessary to do the presentation itself. Beginning presenters and speakers may benefit from participating in formats and venues that have short 10- to 15-minute periods or panels and co-presentations. Opportunities that involve small audiences are also conducive to gaining needed experience.

Graduate Projects/Papers in the Healthcare Professions

During the 1990s, as more educational programs on healthcare professions either began by, or converted to, awarding master's degrees, and later clinical doctoral degrees, theses or dissertation requirements became more common. A final graduate paper typically requires extensive modification, usually a specifically tailored reduction in length, to be a suitable candidate for peer-reviewed publication. The academic format needs to be modified to fit the format required by a specific journal. Editors and editorial board members are expert at determining whether a master's thesis or doctoral dissertation has been reworked to fit the specifications of a journal. Adding early publications to one's resume is likely to enhance employment opportunities and professional advancement. Some healthcare professions' publications do not accept manuscripts from students as a matter of policy, due to the high overall rejection rate of unsolicited manuscripts. If a graduate project is worthy of consideration for publication, then a query letter should be sent to either a member of the editorial board or the editor of a target journal. Acquiring their guidance in advance can increase the chances for publication.

Writing the Paper

Huth proposed a writing system that utilizes a process in which one writes the first draft, places it aside for a couple of days, rereads it, and then begins the second draft (rewrite). This iterative-reiterative process is continued until the paper is finished.[6] Authors should consider sharing the paper with a friend who has critical writing and editing skills. Colleagues with content expertise should also be consulted. It may take as many as 20 or more drafts and rewrites until a final product is achieved. Quality is the aim, and a great deal of effort is needed.

Working with Editors

Writers and editors have historically shared an uneasy alliance. According to Arthur Plotnik in *The Elements of Editing*, editors are foot soldiers in the eternal war between raw talent and the people who process that talent.[7] As long as writers write primarily to advance themselves and editors edit to satisfy readers, there will never be a lasting peace. Writers know their particular subject; editors know their audience. A well-known truism is that knowledge of the subject does not necessarily translate into good writing, and good writing does not necessarily correlate with good editing. The editor may determine that a writer's style does not correlate with the journal's requirements or quality standards. Embrace the editorial review process. All writers need a good editor's touch.

When conflicts of interest arise in the editing process, the readership, not the writer, receives first consideration. During the conflict, the writer must have thick skin. Some of the writing is always changed in the editorial process. Manuscript content is the writer's province, but the form is the editor's specialty. Many manuscripts must be revised a number of times. Each revision is reviewed, and the changes made to meet required or recommended improvements may need further work. Like other biomedical journals, journals in the health professions are typically expensive to operate, and editors are required to make the most efficient use of their printed pages. **FIGURE 16.2** shows the stages of publication.

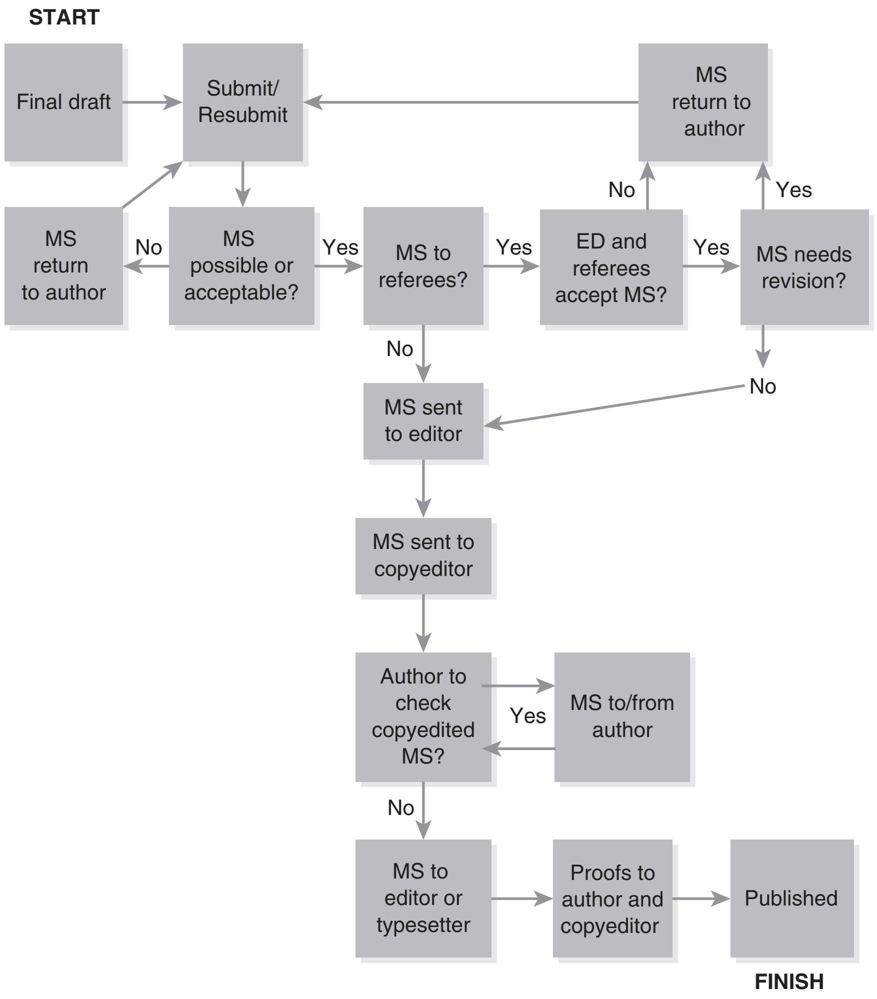
START
Final draft
Submit/ Resubmit
MS return to author
No
Yes
MS return to author
No
MS possible or acceptable?
Yes
MS to referees?
Yes
ED and referees accept MS?
Yes
MS needs revision?
No
No
MS sent to editor
MS sent to copyeditor
Author to check copyedited MS?
Yes
MS to/from author
No
MS to editor or typesetter
Proofs to author and copyeditor
Published
FINISH

FIGURE 16.2 The manuscript process.

Basic Steps in Publication

How is the right journal chosen as a target for a manuscript's publication? Different journals feature different types of formats: original reports, special articles, short papers, editorials (usually invited), clinical notes, and letters to the editor. Initially, the format of the paper should consider the choice of venue and format. If this decision is difficult or problematic, one of the journal's editors or editorial board members may provide clarification. Is the topic of the proposed paper within the journal's scope? Is the topic represented frequently or only rarely? Does the target journal offer the best match of the audience with your topic? What formats does the journal accept? Determine who cares about the message of your paper. Is it best suited for a clinical specialty journal or a general medical journal? Is it best suited for clinicians, educators, researchers, or all of these groups?

Duties of a Potential Author

Based on the topic of the paper, several journals may be publishing candidates. Begin with the most recently published issue of a target journal and carefully read each back issue for at least the past year, then review the last few years' publications. Ensure that an article on the same topic has not been published recently. If it has, determine whether the paper merely rehashes existing information or adds new information. In assessing the suitability of a paper for a particular journal, these guidelines should be followed:

- Read the journal's "Statement of Editorial Purpose."
- Review the journal's editorial board membership.
- Consult the annually published list of peer reviewers.
- Read the journal's most recent "Information for Authors" statement.
- Evaluate the journal's publishing style regarding article format and requirements for tables, charts, abstracts, footnotes, citations, and references.

By performing these tasks, the author can determine in advance whether the project fits a specific journal or if it needs to be modified in certain ways. Has the relevant work of leaders, members of the journal's editorial board, and peer reviewers been reviewed and cited? This aspect of writing is often referred to as "chanting the names of the ancestors." At least one editorial board member and one or more peer reviewers review each provisionally accepted manuscript. If their relevant work is not cited, the paper may be deemed incomplete.

Communicate with the Connected

Dialogue with editors, editorial board members, peer reviewers, or subject matter experts on the research topic is extremely helpful in the publishing process. After a target journal has been chosen, send a proposed outline of the manuscript to determine preliminary interest. Getting from the "unsolicited" to the "solicited" side of the journal's editors is a challenging but worthwhile task to pursue. These are the "connected" people in the publishing realm.

Request Reprints of Previously Published Articles

Every peer-reviewed journal lists the contact person (usually the first author) for article reprints. One way to begin a relationship with professionals is to review their body of work and write a letter stating how much you enjoyed his or her work, combined with a few cogent observations. This individual may end up reviewing your manuscript, or may eventually become a collaborator.

Requirements and Resources for Writers

Writers must develop a thick skin to persevere through the paper's revision, possible or repeated rejection, and the eventual publishing process. Writers must be meticulous in their work.

Students in healthcare professions attempting to meet graduate-degree paper requirements must have access to biomedical literature databases. Basic requirements include access to medical literature databases, preferably accessible electronically via the Internet. Academic reference librarians can be wonderful friends; they can make the literature review and reference retrieval process much less intimidating. Writing also requires uninterrupted time, with ready access to reference and resource material, including reference documents, a personal computer, and other favorite writing aids. Time for writing must be scheduled on a regular and predictable basis. Close the door if necessary, or write from home if that option exists.

The Peer-Review Process

To evaluate the accuracy of submitted manuscripts, most reputable biomedical journals employ the peer-review process. This process typically involves sending the manuscripts to two or three individuals, selected by the editor, who are in a position to judge the value of the work. In more selective journals, only a few submissions ever make it to the peer-review process. These journals often have full-time editorial positions that are filled by healthcare professionals (e.g., physicians and other clinicians) who have developed skills in medical writing and editing. This is the case for journals such as the *New England Journal of Medicine, Journal of the American Medical Association, Annals of Surgery*, and *Annals of Internal Medicine*, among many others.

Manuscripts submitted to journals are privileged communications that are authors' private, confidential property, and authors may be harmed by premature disclosure of any or all of the manuscript's details. Reviewers, therefore, should keep manuscripts and the information they contain strictly confidential. Reviewers should not publicly discuss authors' ideas before the manuscript is published. Reviewers are expected to respond promptly to requests to review and to submit reviews within the agreed-upon time. Reviewers' comments should be constructive, honest, and polite. Reviewers should declare their conflicts of interest and recuse themselves from the peer-review process if a conflict exists.[2]

On receipt, most reputable journals conduct an initial internal review of the manuscript. The editor or an associate editor reads the manuscript and determines its eligibility for peer review. If it is determined to be a candidate for publication, the manuscript is then sent to peer reviewers from various related fields. Often, peer reviewers are editorial board members and/or editorial consultants who perform these services for the journal on a regular basis. The review should occur promptly. Papers may be withdrawn by the authors if a reasonable explanation is not offered for the review taking longer than stated in author guidelines.

The peer-review process is regarded as an extension of the basic principles of science and scholarship. Peer review has existed for more than 200 years and has achieved nearly universal application for assessing research reports before publication. Peer review is considered a critical quality control. Despite this widespread utilization, the process has been shown to have flaws, and relatively little is known about the quality and utility of the information that is eventually published.[8,9]

Blinded Review

Journals vary in their policies about masking or hiding, the names and affiliations of authors when the article is sent to reviewers. Most, but not all, biomedical journals mask the identities of authors. A question regarding the value of the peer-review process is the potential of a reviewer being familiar with the author's identity, which creates a bias. In several disciplines, only a few investigators are involved in a particular field of research, and the identities of authors may be easily recognized by peers. This is the Achilles' heel of the peer-review process that has led some journals to adopt the policy of unblinded review.

The Publishing Decision

Possible outcomes of the peer-review process include the following:

- Acceptance
- Minor revisions required
- Major revisions required
- Outright rejection

The response from the editor typically consists of a cover letter summarizing the reviewers' comments, recommendations, and the blinded reviewers' evaluation sheets. Always pay close attention to recommended suggestions, changes, or critiques. Address all concerns expressed by the reviewers, including data inconsistencies and errors, even if you disagree with them. It is not unusual for authors to disagree with peer reviewers. When the case is well made by the author to retain the original version, the section of the manuscript in question may remain unchanged. Rejection letters with a copy of the submitted manuscript should be reviewed and saved. Some rejection letters are carefully worded invitations to resubmit. Rejection is part of the process. All successful authors have a history of rejection, and none should take it personally. The manuscript may be resubmitted after completing all of the required revisions and addressing all of the concerns of the editor and reviewers.

Submitting the Final Manuscript

Assuming the final version of the manuscript meets all publishing requirements, the packet is then sent to the journal, including the requisite number of manuscript copies. Be aware that the specific format of the title page may vary by the journal (e.g., if an abstract is required as part of the manuscript). The final packet should also be accompanied by a cover letter that summarizes the basic rationale for the paper. The cover letter must also include an author attestation statement that neither the paper nor its essential substance, is presently under consideration by another journal and has not appeared elsewhere (e.g., in another journal). This statement must be fully acknowledged and signed by all authors indicating that the work is their own and has not been published or submitted elsewhere.

Authors must follow precisely the "Instructions to Authors" of the particular journal to which they are submitting. The final draft submission should be flawless. These instructions become very important when work is submitted to a journal in which there is significant competition for space. If an editor must choose between two manuscripts of relatively equal importance, then the one that requires the least amount of corrective action from the editorial staff is more likely to be accepted.

The next step is the receipt of the page proofs. Be prepared for a rapid turnaround requirement; as few as 24 hours is not unusual. The author should drop everything to address the proofs and return them for final typesetting.

Realize that the copyright protection is assigned to the journal that accepts the work; in reality, it is no longer the author's paper. If some of the data must eventually be included in another manuscript (e.g., a published table), permission must be secured from the publisher, regardless of authorship.

Conflicts of Interest, Disclosures, and Institutional Review Board (IRB) Approval

It is standard operating procedure for peer-reviewed healthcare professions journals to include requirements for full disclosure on any real or perceived conflict of interest with the manuscript content, affiliated sponsors, and organizations, or coauthors. This disclosure includes any investment or financial interest or funding associated with any product or organization referred to in the manuscript. Additionally, federal law requires any research involving human subjects be reviewed and approved by a designated and approved institutional or regional institutional review board (IRB) before commencing any research. It is not fully appreciated within the health professions communities that this includes all human subject research, regardless of whether the project includes federal funding. Any research including medical and administrative record data, leftover tissues, health services research, survey, behavioral, biomedical, or any other healthcare research is included in this requirement. Even if the research seems likely to be exempt from IRB approval (e.g., an anonymous survey that is optional to complete), evidence of an IRB-approved exemption must be acquired for biomedical journals to consider the work for publication. Many uninformed researchers have been frustrated when they completed a project and discovered after the fact that IRB approval was necessary, rendering their research unacceptable for publication. This standard applies to research in all healthcare professions.

Authorship

The corresponding and/or first author must carefully select coauthors as the research or project ideas are developed. Adding colleagues or friends who contribute little to the work is inappropriate and serves to alienate the coauthors who perform the work. A coauthor should have generated at least part of the intellectual content of the paper as well as had a part in writing the paper, including reviewing it for possible revision or revising its intellectual content. A coauthor should be able to publicly defend all of the content of the paper in the scientific community.

Criteria for Authorship

In the development of a manuscript, it is important to apply criteria to determine who should qualify as an author. The ICMJE recommends authorship be based on the following four criteria:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work,
2. Drafting the work or revising it critically for important intellectual content,
3. Final approval of the version to be published, *and*
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

The ICMJE further indicates that "in addition to being accountable for the parts of the work he or she has done, an author should be able to identify which coauthors are responsible for specific other parts of the work."[2]

Before a researcher agrees to collaborate, it is wise to know the work habits, reliability, and temperaments of potential coauthors. Are they committed to deadlines? Do they return calls and provide information in a timely manner? Do they do what they say they will do? All of these issues matter when it comes to coauthoring manuscripts. The more coauthors included, the more difficult it becomes to reach consensus about and satisfaction with the paper. It is important to agree up front about work responsibilities and authorship order. The overall responsibility of the manuscript always rests with the first author.

Assignment and determination of authorship on papers submitted to biomedical journals has undergone significant evolution in recent years. Now a greater sense of accountability for the intellectual contributions of authors is the norm. Authorship of a paper submitted to a biomedical journal indicates that the individual has invested substantial intellectual effort in the conceptualization and writing of the manuscript. To qualify as a coauthor, an individual should fulfill the following criteria[10]:

- Participated in the work sufficiently to take public responsibility for all or part of the content
- Made substantial contributions to the intellectual content of the paper in one or more of the following categories:
  - Conception and design
  - Acquisition of data
  - Analysis and interpretation of data

  - Drafting of the manuscript
  - Critical revision of the manuscript for substantive intellectual content
- Statistical analysis
- Obtaining funding
- Administrative, technical, or material support

Today, the most reputable medical journals require authors to sign a form attesting to their input into the paper and verifying their qualification for authorship designation.

Group authorship sometimes presents problems, particularly with citations. Group authorship is the listing of the name of a group in place of the names of individual authors. Modified group authorship, in which individual names are listed followed by the name of the group, is also used. Group authorship is most often associated with studies involving many investigators (e.g., multicenter clinical trials or genomics) because it allows investigators to share credit equally.

PubMed is the National Library of Medicine's (NLM's) bibliographic database, with citations dating back to 1966. In the past, the NLM did not include group authors in the MEDLINE author field; rather, the group name was included as an add-on to the title. The NLM now lists group authors under a separate "collective name" field. The Science Citation Index (SCI) is a scientific and biomedical bibliographic database used to track citations to individual articles. Instead of listing the research group in the author field in its source listing, SCI lists either all individual names in the group or the writing committee members' names in the order they are listed in the article.

Some Challenges for Health Professions Publications

Over the past 40 years, the healthcare professions have seen journals come and go and, in the main, have had difficulty in gaining recognition beyond their professional readership. Part of the problem is the very specialized interest of clinicians for, primarily, clinical review-type articles. Most clinicians are employed full-time and, therefore, do not have the time nor direct incentive to write and publish medical articles. Those that do, primarily educators, are relatively small in number and tend to write on educational and curricular topics and not on clinical matters. Clinicians in the health professions seek material of a clinical nature that will help them to remain current on advancements in medical care and make them more effective in serving their patients.

Thus, many healthcare professionals who might otherwise seek to write and publish are forced to compete with physicians and other biomedical scientists in the biomedical world who are academics, clinical researchers, or basic science researchers, and have the resources and incentives to write and publish. Healthcare professionals usually are not trained to be writers and/or scholars but instead are prepared to be clinicians. Most are in no position to produce original biomedical studies and research products sought by journals. As a result, the healthcare professions literature has tended to focus primarily on concise and current clinical review articles, that is, papers that summarize a specific clinical problem and outline recommended management. Although this focus tends to serve the needs of the primary audience, it does not contain original research material. As a consequence, journals specific to the healthcare professions fail to have a readership beyond their profession. This may change as more students gain research experience as a component of their education, as more health professions educators become involved with research, and as more and more clinicians participate in research as part of their practice.

Medical Journals

Many healthcare professionals, both clinicians, and academics, commonly publish papers in biomedical journals. Those in the nonphysician healthcare professions (PAs, NPs, CNMs, PTs, etc.) at times publish in journals that are aimed primarily toward physician audiences, such as the

New England Journal of Medicine, Journal of the American Medical Association, The Lancet, and *British Medical Journal*, as well as leading specialty journals such as the *Annals of Internal Medicine, Annals of Family Medicine, Health Affairs*, and *Annals of Surgery*.

The modern medical publishing business is an intensely competitive enterprise. Virtually all biomedical journals are dependent on their sponsors (professional societies and commercial publishers) for their viability. The business operations of these ventures, in turn, depend, most of the time, exclusively on advertising revenue. This fact of life (that biomedical publications depend on revenues from advertisers) requires editors and editorial boards to balance scientific direction and standards and journal content with the requirements of those who are "paying the freight" in the operation of the publication.

The vast number of publications in biomedicine are essentially businesses. Publishing medical journals is an expensive venture. Publishers of various biomedical journals comprise the following:

- Professional organizations that sponsor and produce a journal identified as their official journal
- Proprietary publishing firms
- Philanthropic organizations, including journals such as *Health Affairs*, a health policy resource subsidized by Project Hope, or the *Milbank Memorial Fund Quarterly*

Manuscript Flaws That Prevent Publication

Authors fall prey to several pitfalls in the preparation and submission of manuscripts to biomedical journals (**BOX 16.2**). Editors and reviewers are always looking for reasons to be skeptical regarding the worthiness of a manuscript for publication. Although the reasons for rejections are extensive, the author should bear in mind the following common scenarios:

BOX 16.2 Reasons for Manuscript Rejection

Excessive use of philosophy
Loose organizational style
Material not sufficiently important
Information not easily generalized
Unclear what methods were used
Results described in an unclear way
Statistics used incorrectly
Sample size inadequate
Conclusions unwarranted
Results not compared with similar studies
Inadequate period of observation, use, or evaluation of the method
Inadequate review of the literature

Data from Geyman JP, Bass MJ. Communication of results of research. *J Fam Prac*. 1978;7(1):120.

- The topic is inappropriate for a specific journal. The manuscript is a sound piece of investigation, description, or opinion and is presented in a suitable format, but the topic is not appropriate for a particular journal.
- In some cases, these papers may represent previously rejected or recycled manuscripts that the author(s) did not bother to reconfigure in the required format for that journal.
- The use of imperfect style and "crazy-quilt" fonts. A manuscript containing imperfect style that has differing sections with differing fonts and font sizes indicates that it may be a "cut-and-paste" effort, one that is recycling the work of others or an uncoordinated collaboration among authors that has not been properly edited. Manuscripts with these types of sloppy narrative reveal inattention to detail and a nonsystematic structure. Editors regard such papers as a waste of time because it appears the authors have not put forth the proper effort to prepare the manuscript to specifications.
- "Cut-and-paste" citations were used. Cut-and-paste citations lifted verbatim from reference sources are ill advised. If a citation is not physically available, then do not quote it. Do not be surprised if editors or reviewers ask for verification, particularly if the citation looks suspicious. If this verification falls

short, it raises questions of plagiarism, and the paper will be summarily rejected.

- Tables and/or text were used without permission. Give credit where credit is due. Acknowledge the source if a table from someone else's work is copied or modified for use. Provide the required permissions to the publisher.
- Errors in mathematical calculations occurred (bad math). Be aware that the journal will calculate any math included in the manuscript, such as percentages in a table. It is always recommended authors double-check their data, including the math in tables.
- The same material was used to publish several articles. Editors are well acquainted with the tendency of authors to partition their work into "least publishable units," a phenomenon also known as "salami science." In this case, a data set is split into smaller subsets, each with a narrow focus, to publish as many papers as possible from one core data set. Examples include submitting single-center reports from multicenter studies and short-duration reports from long-duration studies. The dangers of repetitive publication of the same material are many. An old or recycled paper must be sufficiently updated or have new data added to justify publication.
- Citation or reference inaccuracies were found. Authors are obligated to double-check the accuracy of all citations within their work. Citation error is a serious problem in biomedical publications. One study of peer-reviewed surgical journals found a 48 percent citation error rate, casting doubt in many cases that original reference sources were reviewed by the authors.[9]

On Writing and Publishing

Writing is difficult and time-consuming work. Authors must fundamentally calculate the questions of "Why write a paper if it does not stand a reasonable chance of being published?" and "What do I have to say?" Dr. John Billings, the founder of the National Library of Medicine, espoused four primary rules for the aspiring author:

1. Have something to say.
2. Say it.
3. Stop as soon as you have said it.
4. Give the paper a proper title.

Alternatively, as Stephen Locke, former Editor of the British Medical Journal put it: A good paper/article has a definite structure, makes its point, and then shuts up.[9]

Strive to Write Clearly

Clear thinking leads to clear writing. George Orwell said, "Good prose is like a windowpane; that is, what you have to say should not be obscured by how you say it."[11] Prose is bad when readers need to stop and look at it again to understand its message. The central message of a book written by a long-time editor of *JAMA* was embodied in its title, *Why Not Say It Clearly?*.[12] Interestingly, this book appeared during a time when biomedical writing was criticized by, among others, the late Michael Crichton (a well-known author and film and television producer), who was then a recent medical school graduate, as being deliberately "obfuscatory." Writing clearly means using words with the greatest degree of accuracy in transmitting what you wish to communicate to others.

Summary

After deciding to attempt to publish a paper that results from a research study, several key steps should be considered. These include making sure the paper is a quality effort, and the writing is clear and concise. Authors must carefully select the journal or journals that may be interested in the type of work that has been produced. The editor may be contacted about his or her interests. The "Instructions for Authors" should be followed explicitly. If the journal is interested, cooperate on revisions and suggestions for the paper.

This process takes time and patience, sometimes up to 1 year. There may be many reasons for the rejection of a submission; rejection is not personal. In fact, for those who seek to publish often, rejection is part of life. Remember that the work has value in the experience gained in the process of scientific inquiry. If research is an ongoing part of a healthcare professional's life, publication success will eventually occur with perseverance.

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CHAPTER 17

Interpreting the Literature

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CHAPTER OVERVIEW

The U.S. National Library of Medicine holds more than 24 million biomedical articles published since 1966.[1] For most clinicians, wading through even a small number of journals or articles can be daunting. Medline indexed 1,279,200 articles in 2017.[2] The challenge is to remain current and meet the expectations of the informed healthcare consumer.

Healthcare professionals must be able to keep up with the rapid changes in their field by interpreting the scientific and medical literature. The role of textbooks is to provide a good foundation, but current literature is the key to modern practice. Professional journals are the main source of current information for many clinicians.

The essential question for every clinician is: What is important to my patients and my practice? Answering that question is the key to providing contemporary and effective care. Part of the answer lies in developing skills that critically examine the literature to answer those questions. This chapter guides clinicians who are interested in a systematic approach when interpreting the literature.

LEARNING OBJECTIVES

- Identify professional journals for a healthcare profession.
- Define the key elements in the interpretation of the literature.
- Identify, list, and discuss the steps in evaluating the medical literature.
- What questions should be explored in the interpretation?
  - Is the problem identified and defined?
  - Is the design appropriate?
  - Are the analyses appropriate for the design and data?
  - Is the conclusion based on the results?
- Develop an understanding of the general approach to reading and interpreting the healthcare literature.

Introduction

Interpreting the medical literature is a process of integrating, synthesizing, and summarizing information obtained from different sources into a recommendation for practice. The intent is to apply the best knowledge available to make the best choice for the circumstances encountered in the clinical setting. Summaries of this information, known as integrative literature, come in many forms: systematic reviews, overviews, meta-analyses, practice guidelines, decision analyses, and cost-effectiveness analyses. The concept of evidence-based medicine is expanding, and the extraction of evidence from the literature into practice, although logical, presents some challenges. Busy clinicians must develop skills that allow them to become critical consumers of select literature and decide what applies to their patients. This process comprises "the application of the best available evidence to patient care."[3] The patient's perspective should always be considered as part of evidence-based decision making. Decisions made with evidence and patient involvement enhance care.

Literature interpretation is a skill that must be learned, practiced, and applied. As more healthcare research articles are reviewed, the results can sometimes be confusing, conflicting, and confounding. Clinicians must develop interpretation skills over time. If the literature is not continually read and effectively analyzed, clinical practices will become stale and even possibly incorrect.

The more immersed in research healthcare practitioners are, the greater their ability to synthesize and utilize the literature. Novices become experts in interpreting the medical literature by deliberate practice. This chapter provides basic questions that should be asked by the reader when reviewing a biomedical publication.

The literature search is often a quest for theory building. It also helps the researcher discover what research has been done and how it could be done better or differently. The scholar's research should say something new or validate existing work, while it connects with research that already has been reported. The literature provides a foundation in theory and topics of concern. How the literature is interpreted influences the overall research process. By interpreting the literature, the practitioner develops a knowledge base and the ability to make a case for a new investigation.

Interpretation of the literature takes on greater importance when it involves the care of others. Misinterpretations can lead to significant errors in healthcare practice. This chapter is based on several resources[3,4] and the authors' experience to provide a general guide for how to interpret the medical literature.

Interpreting the Literature

First Things First

The first step to literature interpretation is to read enough background information on the subject to understand as many aspects as possible of the issue being studied. Most healthcare professionals have developed some literature interpretation skills by reading or studying various resources in their fields. An initial step in literature interpretation is to understand specific terms used in research (e.g., percentages, means, validity, limitations, probability, subjects, and population). Recognizing the meaning and significance of research terms becomes more natural as the ability to interpret the literature progresses. Furthermore, incorporating such terms in the context of research also becomes more comfortable as experience is gained from understanding the literature. One suggestion is never to let a term go undefined while reviewing the literature, especially if the material is vital to the clinician's research projects, clinical practice, or patient care. Another suggestion is to develop a bibliography of useful references. Historically, researchers had to find a way to file important articles. Now, most journal articles are available online and can be quickly accessed.

The Scientific Method

The principles of the scientific method are integral to the literature process (searching and interpreting) because the emphasis is placed on gaining knowledge from the rigorous process of systematic observation, analysis, and reasoning. Schematically, all concepts must pass through the scientific method corridor. This process adds value and becomes part of one's fundamental knowledge. Therefore, the literature search must include and incorporate scientific observation and data collection. The formal process of acquiring scientific knowledge, whether through reviewing the literature or recording observations, must be conducted in a reproducible manner. In essence, this means any competent clinician could replicate the literature search and reach the same conclusions. A researcher incorporates the scientific method into his or her project by defining each step as follows:

1. *Problem:* A precise statement of what knowledge was sought and why it was sought
2. *Question:* A single sentence that asks a question related to the problem
3. *Method:* The plan of how the research was done and how the knowledge was gained
4. *Results:* Unequivocal statements of the knowledge that was gained
5. *Interpretation:* Application of the knowledge gained

How the results of this process are interpreted is key to understanding how the results will be utilized to provide better care for patients. Recognizing the steps of sound scientific investigation, as well as applying scientific concepts, will help the clinician interpret the results in a meaningful manner.

Questions to Ask (and Answer)

Whether interpreting the literature for application in practice or gathering data for a research project, part of the task and challenge of reviewing literature is to assess what has been published on the topic of interest. **BOX 17.1** outlines a set of questions to be asked and answered before making any assumption about the literature.

BOX 17.1 Questions to Ask and Answer

1. What is the source (journal) of the article?
2. Was the publication peer reviewed?
3. Who are the authors and what are their affiliations?
4. What (or who) is the main subject of the study?
5. What problem(s) were investigated?
6. What is the purpose or rationale for the study?
7. Who or what constituted the sample or population?
8. What was the design of the study?
9. What statistical analyses were used?
10. What are the results?
11. Are the results clear?
12. Did the results answer the identified questions?
13. Do the results seem valid?
14. Are the interpretations (conclusions) of the results consistent with the study design and analysis?
15. Are the results consistent with findings from similar studies?
16. What do the results mean to you and your patients?
17. Can the results be applied to your research or clinical practice?

Ultimately, this method of literature inquiry or evaluation eventually becomes second nature as it is practiced. Writing down answers to these questions while evaluating an article reinforces the steps toward becoming a critical evaluator of literature. New questions may emerge as well during this process. While reviewing various information sources, new thoughts on evaluating the literature tend to emerge. Such thoughts and concepts precipitate the development of an individual research style and process. Only through scrutiny, analysis, and replication can consumers of the literature ask the right questions, challenge the answers, and find answers to more questions. The scientific process and the information that results from that process are then validated. This process defines the cumulative development of scientific knowledge.

Significant Questions to Ask When Evaluating the Literature

1. *What is the source (journal) of the article?*

   The reputation of a source can be as crucial as a citation. Journals that tend to have the highest subscription rate typically have a higher degree of prestige. The top journals in a specific discipline are most often cited due to their solid reputation in the medical community. For clinical articles, these include the *Journal of the American Medical Association* (*JAMA*), *New England Journal of Medicine*, and *Lancet*. However, other lesser-known journals also publish high-quality work. Each journal is ranked according to citation rates. Although lower-ranked journals can publish sound scientific articles and higher ranked journals can publish articles of poor quality, the ranking system is a helpful measure of quality.[3] Each publisher has a set of standards related to manuscript acceptance. Journals with high submission rates and low acceptance rates are often considered stronger sources than those with low submission rates and high acceptance rates. Also, the journal's impact factor can be an important metric when comparing the relative value of a journal title within its field. The Journal Citation Reports at ISI Web of Knowledge is a database that can be utilized to research this information.

2. *Was the publication peer reviewed?*

   Peer review is a process of manuscript critique by someone familiar with the same body of literature that the author is submitting. Since the 1950s, the majority of scientific manuscripts submitted for publication undergo a peer-review process. This review is intended to evaluate a manuscript critically, so the reader is offered some confidence that the resulting publication has been scrutinized for soundness, valid results, and conclusions that fit the findings. Journals are ranked by their scientific merit and readership. Readership often rests on the journal's ability to provide new and useful information that can be confidently accepted. However, not every article in a peer-reviewed journal is necessarily subjected to the peer review process. Many journals have individual sections or features that have a different manner of review or oversight. An article can be in a peer-reviewed journal but undergo a different process than peer review.

3. *Who are the authors and what are their affiliations?*

   The reputation of the author(s) can be significant, particularly for controversial findings. Experts in a particular field may know many of the contributors to their body of literature. For the person just entering the field, time is needed to familiarize him- or herself with subjects and the important names. To help feel confident about the literature you are reviewing, you may have to do some homework on the reporting media and the authors, particularly if the literature concerns important discoveries or contributions. You may recognize the work of some authors and the reputation they bring to the literature. On the other hand, a note of caution is needed before accepting every finding regardless of the source or author. The author's affiliation can have some influence in your consideration of a reported study. Certain institutions and universities tend to be centers of excellence in particular areas of science and learning. These institutions tend to attract a body of scientists and writers expanding work in a specific area. Being aware of this aspect of the research helps the reader understand the authors' perspective and what may have influenced their work environment. It also helps the reader to understand why the investigators are studying these particular problems in the first place. Be aware that some authors work for industry and may have obvious conflicts of interest.

4. *What (or who) is the main subject of the study?*

   The answer to this question may be the same as, or similar to, the problem investigated. Depending on the type of investigation, the main subject could be different from the problem. For example, in a study of student test-taking performance, the subjects of the study are the students; however, the problem investigated could be how the students study for tests, how they act during tests, and/or what they remember after the test. In health care, the subject of a research study could be cholesterol, but the problem investigated could be cholesterol's response to some intervention.

5. *What problem(s) were investigated?*

   The answer to this question should be self-evident from the text. The research problem is the issue or topic of focus. For example, perhaps a healthcare professional knows little about the career patterns of female EMT-Paramedics. The problem presented is the difficulty in predicting how long various types of EMT-Ps will remain in the workforce. Healthcare economists and labor experts need to address these questions for education or implementation of health policies. The research question is always a narrower aspect of the research problem. The hypothesis is a method of addressing a research question. Research questions and hypotheses should be clearly stated and linked to the problems being investigated. Also, any assumptions made by the investigators should be assessed. Assumptions can confound and influence the study and report.

6. *What is the purpose or rationale for the study?*

   This question is the "why" of the study. Why was it done? What purpose did it serve? Was it a significant problem? In research, many questions can be asked; however, for research literature to be valid, the questions should serve a useful purpose with a sound rationale for its undertaking.

7. *Who or what constituted the sample or population?*

   The sample size is often critical for population research. Who or what was studied and how many were in the sample or subsamples studied should be clear. It is important to understand this aspect of the study, especially when applying the results in a healthcare setting or with patients. The number of subjects studied can affect outcomes: too small a number may not be representative or may miss a pertinent factor; too large a number may minimize some important findings. To extrapolate data and apply them outside a study, the characteristics of the sample must be evident and comparable to the population from which the sample is selected. However, what may be true for one group of individuals may not be true for another, so results should always be considered cautiously.

8. *What was the design of the study?*

   Often the design of the study is critical to the outcome. The methods should be described in enough detail to allow the reader to make conclusions about the results and applications. Each study design is susceptible to limitations, threats to validity, threats to statistical analysis, and threats to conclusions. Even the fundamentally sound randomized assignment, double-blind studies have limitations. Clinicians should become familiar with the limitations of the various types of studies and look for biases in study design, because these flaws may affect conclusions and interpretation of the results.

9. *What statistical analyses were used?*

   Were the appropriate data analyses performed for the data type and study design? A statistics book is a handy resource; it may also be a good idea to consult a statistician. Statistics can be confusing, and even experienced researchers make mistakes. Observe carefully how the data were analyzed. Do the data and statistical analyses make sense? Sometimes reviewing the statistics may be helpful in understanding the results and conclusions.

10. *What are the results?*

    The results should be reported as unambiguously as possible. Two researchers undertaking the same study should report their findings in similar ways without any subjective interpretation. Determine whether the results of the study seem consistent with the study design and the analyses used. Do the data make sense and are the results consistent with current knowledge? Analysis results that indicate extremes should be examined carefully.

11. *Are the results clear?*

    Do the results have meaning to the intent of the study? Are they understandable? Are they consistent with the methods and analyses proposed? When results are not clear, either the study was conducted confusingly, or the methods are unfamiliar.

12. *Did the results answer the identified questions?*

    The results may not be expected, but that does not necessarily mean they are wrong. If the methodological process was conducted correctly, then the results should stand alone, and the majority of readers should draw similar conclusions. Results should answer the questions posed earlier in the study. Although the answers often lead to more questions, the primary research questions should be addressed in the Results section.

13. *Do the results seem valid?*

    Validity is at the heart of most studies. Validity is defined as making common sense and being persuasive to the reader. The major categories of validity are internal and external validity. If a research study has been performed correctly without errors, then the study is considered to be internally valid. If the study represents the realities found in the general population, then it is considered externally valid.

    External validity is threatened when:

    - The source population is not described well.
    - The eligible population is not described well.
    - Study participants do not represent the eligible population.
    - Information is lacking about the participants at baseline.
    - Interventions studied could not be easily replicated in real life.
    - Follow-up time was too short.

    Internal validity is threatened when the study is conducted in a biased way. The following are common sources of bias:

    - Selection—some characteristic in a selected group inappropriately influences the study results
    - Observer—person taking the measurements is not objective
    - Participant—the subject's behavior does not follow study protocol
    - Withdrawal—20% or more of the participants drop out of the study
    - Recall—relying on human memory to quantify outcomes
    - Measurement—problems with the instruments used to assess outcomes
    - History—factors outside of the study influence the results
    - Maturation—the results are altered by the passage of time alone
    - Positive publication—positive results more likely to get published than negative results

    Face validity means that the results of a study can be taken at face value. Because of vagueness and subjectivity, psychometricians abandoned this concept a long time ago. However, when reading an article, one may get a sense that something does not seem right, especially if the reader is very knowledgeable about the topic. This represents a problem with face validity. Construct validity assesses the degree to which the measure relates to other variables as expected within a system or theory. In contrast, content validity is the extent to which the method of measurement includes all of the major elements relevant to the construct being measured.

14. *Are the interpretations (conclusions) of the results consistent with the study design and analysis?*

    Here, the authors of the article make the correct conclusion about the data. However, this area can be open to personal bias and misinterpretation. The reader, therefore, has to determine whether the conclusions are consistent with the type of information provided by the study design.

15. *Are the results consistent with findings from similar studies?*

    One should have a sense of the problem, either from previous literature reviews or one's own clinical experience. Studies that deviate significantly from what is already known should be examined with caution. However, this deviation does not mean the study is wrong. Occasionally, discoveries emerge from unexpected or unanticipated results.

16. *What do the results mean to you and your patients?*

    This question may be the most important one the clinician can ask. What do these results mean to your practice and to the people for whom you provide care? For medicine and health care, it is important to examine the validity of an intervention to make sure it applies to the patient population. The risks and benefits of an intervention study should be clearly understood, as well as what the results mean to the patients' overall well-being.

17. *Can the results be applied to your research or clinical practice?*

    This is a practical question. The results may be valid and important, but you must consider whether or not you can replicate them in your setting.

Evidence-Based Medicine: A New Way of Looking at the Medical Literature

A general assumption has developed that if something claims to be "evidence-based," it is the guiding light for practice. However, the key to evidence-based medicine is the applicability to patient care. The evidence-based concept does not replace clinical experience and/or expertise. Evidence-based research should bridge the gap between rigorous research and clinical investigations for the clinician, ultimately for the patients' benefit. Evidence-based outcomes can come from research studies or the synthesis of existing data and outcomes (e.g., meta-analysis). Regardless, the "evidence" must still be interpreted or evaluated as it relates to the needs of patients.

Friedland et al.[4] have developed a straightforward approach to evaluating evidence-based medicine. This five-step approach is presented in **TABLE 17.1**.

Although this is a concise approach, it does not eliminate the need to ask and answer the previous questions. The table outlines a process that is a part of a broader evaluation and interpretation scheme of medical literature.

Two statistical calculations can be very useful when interpreting the results from a randomized, controlled trial of a new therapy. These two calculations are the number needed to treat (NNT) and the 95 percent confidence interval (CI). Each of these calculations is used for different types of data. Remember, it is important to be aware of the type of data reported by the literature being reviewed.

TABLE 17.1 A Five-Step Study Guide for Evidence-Based Medicine

Step	Question to Ask	Evaluation Points
Step 1	Do I want to evaluate the study?	Is it interesting, novel, relevant?
Step 2	What are the research question, study design, study findings?	What are the populations studied, variables, study design, results, outcomes, findings, and/or conclusions?
Step 3	Are the findings believable?	Do the subjects and variables represent the research question? Are the findings attributable to chance, biases, or confounding variables? Are the findings believable in the context of existing knowledge?
Step 4	What are the important findings?	Are the findings clinically relevant?
Step 5	Will the study help my patients?	Are the subjects similar to my patients? Are the interventions applicable to my patients? Will the findings/outcomes result in an overall benefit for my patients?

Data from Friedland DB, Go AS, Davoren JB, Shlipak MG, Bent SW, Subak LL, Mendelson T. *Evidence-Based Medicine: A Framework for Clinical Practice*. New York: Lange Medical Books/McGraw-Hill; 1998:145–246.

The NNT calculation is used when the article being reviewed contains categorical results (e.g., improved versus unimproved) and two groups (e.g., treatment and control). The NNT is intuitive and helps clinicians communicate the expected outcome of a selected therapy.

The 95% CI calculation is used to compare the means (i.e., the central tendency) and standard deviations (i.e., variability) of a continuous measure (e.g., blood pressure) between two sample groups (e.g., treatment and control). The 95% CI determines the potential range of possible values present in the overall population based on the sampling scheme used in the study. Sometimes the calculated CIs overlap. This overlap is an indication that the treatment studied may be no different from the placebo or control treatment when it is used in a population larger than the study's sample.

To calculate the NNT, some basic rates are first calculated and applied, as shown in the formulas in **TABLE 17.2**. Here are the steps:

1. Calculate the experimental event rate (EER).
2. Calculate the control event rate (CER).
3. Calculate the absolute risk reduction (ARR).
4. Express the ARR as a proportion and divide into 1.

The NNT to produce the intended clinical outcome can then be assessed. Be aware that the formula changes depending on the outcome being measured (i.e., a reduction in bad events or an increase in good events).

Many papers include the 95% CI of the mean in the publication. When it is not given, it is essential to perform a quick calculation. To calculate the 95% CI for a mean when using a continuous measure, the mean, standard deviation, and number of subjects must be known for each group. If any of this information is missing or if the outcome measure does not contain continuous data, then the calculation cannot be performed (**FIGURES 17.1** and **17.2**).

TABLE 17.2 Calculating Event Rates (ER), Absolute Risk Reduction (ARR), and Number Needed to Treat (NNT)

	Control	Experimental
Event	*a*	*b*
No event	*c*	*d*
Totals	*a* + *c*	*b* + *d*
Event rate	Control event rate CER = *a*/(*a* + *c*)	Experimental event rate EER = *b*/(*b* + *d*)
Measure	The experiment reduces the bad event.	The experiment increases the good event.
Relative risk reduction	(CER – EER)/CER	(EER – CER)/CER
Absolute risk reduction	CER – EER	EER – CER
Number needed to treat	1/ARR	1/ARR

Here are the steps:

1. Calculate the standard error (i.e., the standard deviation divided by the square root of the number of subjects in the sample).
2. Determine the constant from a table if the number of subjects is < 60; otherwise, use the constant 1.96.
3. Multiply the constant (usually 1.96) times the standard error from step 1.
4. Add the result from step 3 to the mean of the sample to get the upper confidence limit.
5. Subtract the result from step 3 from the mean to get the lower confidence limit.
6. Perform these steps for both the control and experimental groups to see if the limits from each group overlap.

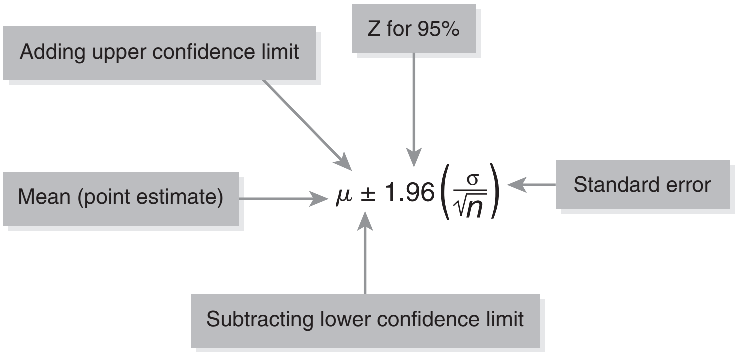
Adding upper confidence limit
Z for 95%
Mean (point estimate)
$\mu \pm 1.96\left(\frac{\sigma}{\sqrt{n}}\right)$
Standard error
Subtracting lower confidence limit

FIGURE 17.1 Formula for 95% confidence interval of the sample mean for n > 60.

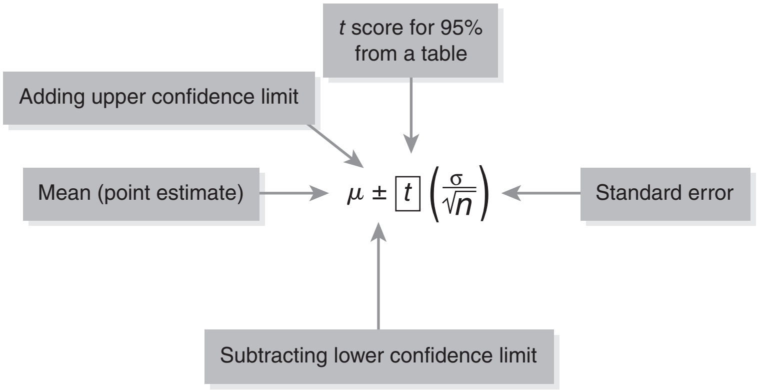
t score for 95% from a table
Adding upper confidence limit
Mean (point estimate)
$\mu \pm \boxed{t}\left(\frac{\sigma}{\sqrt{n}}\right)$
Standard error
Subtracting lower confidence limit

FIGURE 17.2 Formula for 95% confidence interval of a small sample.

If the confidence limits overlap, then no difference in the treatments is likely to occur when they are administered to a larger target population.

The last consideration in the interpretation of evidence-based literature is the level of evidence (**TABLE 17.3**). When studies are analyzed for best evidence, a rating system is used. This evidence rating can be a guide for clinicians regarding the strength of the evidence and its source.

In addition to the evidence-level rating, qualifiers are also used to describe the source of the evidence (**TABLE 17.4**).

Another presentation format for evidence-based medicine is the POEM or Patient-Oriented Evidence that Matters. The POEM is a commercially available format in which the evidence-based medical literature is reviewed and summarized.[5] The intent of the POEM format is to present evidence-based results in a concise and easily readable way that is applicable in clinical practice. Some journals have a POEM section or a POEM feature. These types of summaries are beneficial, but for those interventions or outcomes that affect patients, the original work should always be reviewed.

TABLE 17.3 Levels of Evidence

Level	Description
A	High-quality evidence that considers all important outcomes: randomized controlled trials (RCTs), well-done systematic reviews of RCTs, meta-analyses, systematic reviews using comprehensive search strategies
B	Well-designed, nonrandomized clinical trials: systematic reviews of studies other than RCTs with appropriate search strategies and well-substantiated conclusions, lower-quality RCTs, cohort studies, case-control studies with nonbiased subject selection and consistent findings, quality retrospective studies, certain uncontrolled studies, well-designed epidemiologic studies with compelling findings
C	Consensus or expert opinion

Data from Siwek J, Gourley ML, Slawson DC, Shaughnessy AF. How to write an evidence-based clinical review article. *Am Fam Physician*. 2002;65(2):251–258.

TABLE 17.4 Level of Evidence Modifiers

Modifier	Description
1	Nonrandomized clinical trial
2	A systematic review of nonrandomized clinical trial
3	Lower quality of randomized clinical trial
4	Clinical cohort study
5	Case-control study
6	Retrospective study
7	Uncontrolled study
8	Epidemiologic study

Data from Siwek J, Gourley ML, Slawson DC, Shaughnessy AF. How to write an evidence-based clinical review article. *Am Fam Physician*. 2002;65(2):251–258.

A General Approach to Reading the Literature

Asking all the right questions, going through all these steps, and reading as much as possible is still very time-consuming. Many resources are available that can be easily accessed. Still, the amount of information available is overwhelming. With more than 2 million biomedical publications per year,[1] developing an approach to reviewing the current medical literature is an essential professional skill. However, no single approach works in every situation. A general approach follows, but it may be modified in many ways.

1. Identify the journals that are pertinent to the specialty of interest.
2. Develop a strategy for reviewing those journals.
3. Set aside a specific time each week when journals can be reviewed. (Allow ample uninterrupted time for reading and review.)
4. Identify those articles of interest by their title or by reading their abstracts.
5. Make a quick review of the tables and figures.
6. Decide to read the article.
7. Apply the techniques for interpreting the article.
8. Apply the results to your practice.

Summary

Interpreting the literature involves synthesizing information from different medical, healthcare, and scientific studies and integrating pertinent outcomes into the healthcare practice. Healthcare professionals must develop a sound process for reviewing and evaluating medical literature. Skilled interpretation of the medical literature incorporates up-to-date information that benefits patients. Professionals who fail to stay abreast of the medical literature may quickly fall behind and lose competency. As evidence-based analyses increase, so does the pressure for practice trends to follow that evidence. However, evidence must be balanced with clinical experience and expertise to support the highest likelihood of improved patient outcomes.

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Appendix

Funding Research: Grants

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Appendix Overview

Research is not free or inexpensive. In fact, research is a large enterprise in many universities, colleges, and schools. For many researchers, finding funding is as much a part of the process as the research itself. Grant support is one funding method that is available from many sources, from governmental agencies at every level of government to charities, foundations, business, and institutions themselves. This appendix was developed as an introduction and outline for students and healthcare professionals seeking small or non-governmental grants.[1]

Introduction

Every research project costs something. The cost can be low for small projects that do not require many resources, or very expensive requiring salaries, supplies, consultants, overhead, and more. Grants can be a method of funding all or part of a research project. For students, the most likely source for grant funding is their institution or their health profession's organizations and foundations. Funding may be hard to locate and require some steps to gain, but lack of effort will not provide anything.

The first challenge is to find an agency that will offer a grant. An Internet search will yield a large number of possibilities, probably more than anyone will ever be able to explore. Limit searches by the objective or subject of the project. If the project involves a certain condition, search for organizations that revolve around or involve that condition. For example, if a project involves diabetes, an excellent place to begin is the American Diabetes Association. If the project involves a specific health profession, then look at the professional organization's website for possible support. Never waste time applying for grants with any organization that does not have a relationship, interest, or involvement with the objectives of a project. Make contact with the organization and briefly describe a project to ascertain if it is the type of project for which funding could be obtained. Some key considerations:

- What is the overall purpose or mission of the organization's grant program? What is its significance?
- Does the organization provide grants to support higher education, specifically healthcare professions education or student projects?
- What types of projects does the foundation support? Are student projects eligible for support?
- Are there any specific restrictions on who can receive grants?
- Is the funding range adequate to meet the project needs?

- What is the application process, including deadlines?
- Most importantly, who is the person identified as the grant program director for the organization? This is the person to contact.

What to Do

1. Contact the grant program director. Discuss your concept to ascertain if the organization will fund the type of project you want to do.
2. If funding is possible, follow grant directions exactly. Be clear, compelling, and convincing (the three Cs of grant writing).
3. Describe the project in its entirety. The following questions should be addressed in the required format for the grant:
   a. What problem will be addressed, and in what population? The problem statement should identify an unknown, a phenomenon that is not understood, or something that has been problematic to accomplish. Address a gap in knowledge. What is the project's significance?
   b. What is the purpose of the project? What, precisely, is proposed?
   c. What will research question(s) the project answer? *Alternatively,* what hypothesis will be tested?
   d. What methods will be used to answer these questions or test the hypothesis? Will the methods provide the needed data?
   e. What outcomes will be measured (i.e., what data will be collected)? Does the analysis include the proper tests for the type of data collected? What do the statistical tests to be done tell the investigator?
   f. What will be learned if the project is conducted (i.e., what is the benefit)? How will the gap in knowledge be addressed?

Useful Tips When Applying for a Grant

1. Be concise and use everyday, direct language. Be specific. Do not waste words. Do not try to impress reviewers by using "big" words.
2. Stay on target. Address only the project and its aims, goals, or objectives. Do not drift off the subject. Give the who, what, when, where, and how of the project.
3. Stay within the grant format for page or section lengths. The grantor's requirements must be met.
4. Develop a realistic and accurate budget. Be able to justify all expenses. Use grant money only as specified in the budget.
5. Be prepared to negotiate with the grantor.
6. If the grant is awarded, know the deadlines and meet them.

Conclusion

Grants can be a method to cover the costs of a research project. The information in this appendix is very limited. Much information about grant writing is available. Use it to help in your efforts to acquire grants.

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Glossary

A

a priori: By reasoning from self-evident facts (literally "before").

abstract: The summary of a study in clear and concise terms. Usually limited to 100 to 250 words.

accuracy: The extent to which a scale correctly represents the amount or classification of a variable.

alpha (α): Level of significance or cutoff point used to determine whether the samples being tested are members of the same population or of different populations. Alpha is commonly set at .05, .01, or .001.

analysis of covariance (ANCOVA): A method of removing pretreatment variations (as measured by the control variable) from the posttreatment means (criterion variable) before testing the significance of the posttreatment differences among the groups. ANCOVA provides a basis for ruling out pretreatment differences when the interest is in testing posttreatment differences.

analysis of variance (ANOVA): A statistical method that tests the difference between two or more means when studying groups. Independent variables are nominal (categorical) values and dependent variables are interval values. Asks whether the squared variation of the case scores around their treatment means (*within*) is greater than the squared variation of the means themselves around the grand mean (*between*). These two totals are expressed as a ratio. Comparison of variances reflects different sources of variability, that is, *within* versus *between*.

analysis of variance, one-way: Only one independent variable is manipulated. See *analysis of variance (ANOVA)*.

anonymity: Condition in which subjects' identities cannot be linked to their individual responses.

applied research: Research designed to answer practical questions.

artifact: Something observed in a scientific investigation or experiment that is not naturally present but occurs as a result of the preparative or investigative procedure.

artificial intelligence (AI): The theory and development of computer systems able to perform tasks that normally require human intelligence, such as visual perception, speech recognition, decision-making, and translation between languages.

assumptions: Statements taken for granted or considered true, even though they have not been scientifically tested.

attributes: Characteristics of persons or things (e.g., age, eye color).

attrition: The loss of participants during the course of a study. Attrition can introduce bias by changing the composition of the sample initially drawn, particularly if more subjects are lost from one group than another.

average: An ambiguous term generally suggesting typical or normal. The *mean, median*, and *mode* are specific examples of mathematical averages.

B

baseline measure: The measurement of the dependent variable before the introduction of an experimental intervention.

beneficence: The principle that one should do good and, above all, do no harm.

bias: That quality of a measurement device that tends to result in a misrepresentation of what is being measured in a particular direction. For example, the questionnaire item "Don't you agree that your physician is doing a good job?" is biased because it encourages favorable responses.

bibliography: A list of source materials or references that are used or consulted in the preparation of a work. The references of the bibliography are usually cited in the text.

blind: Blinding is a procedure in which one or more parties in a trial are kept unaware of which treatment arms participants have been assigned to, in other words, which treatment was received.

brainstorming: Group discussion to produce ideas or solve problems.

C

case study design: Intensive exploration of a single unit of study, such as a person, family, group, community, or institution.

causal relationship: Relationship between two variables where one variable (independent variable) is thought to cause or determine the presence of the other variable (dependent variable). Three criteria must be satisfied: (1) the cause precedes the effect in time, (2) the two variables are empirically correlated with one another, and (3) the observed correlation between the two variables cannot be explained away as being due to the influence of some third variable.

central limit theorem: A theorem stating that even when statistics, such as means, come from a population with a skewed (asymmetrical) distribution, the sampling distribution developed from multiple means obtained from that skewed population tends to fit the pattern of the normal curve.

central tendency: A statistical index of a typical set of scores that comes from the center of the distribution of scores. The three most common indices of central tendency are the mean, median, and mode.

chi-squared (χ^2): A test to assess whether observed frequencies of nominal data differ from expected frequencies. A nonsignificant value indicates the classes are independent. A significant value indicates an association. Range is zero to infinity.

citation: The reference to an authority or author of a document.

clinical investigation: The systematic study conducted for evaluating a product such as a drug, device, or biological substance in the treatment, prevention, or diagnosis of a disease or condition using human subjects and to determine the product's benefits relative to its risks.

clinical trial: The scientific investigation of a new treatment that has shown some benefit in animal or laboratory studies, but that has not yet been proven effective in humans.

coding: The process of transforming qualitative data into numerical symbols. Often done for computer input prior to analysis.

coercion: To compel someone by threat of harm or excessive reward to do something they would not ordinarily undertake (e.g., obtaining participants for dangerous research projects by offering large sums of money).

cohort study: A study in which some specific group is studied over time, although data may be collected from different members in each set of observations (e.g., a study of the clinical practice of physician assistants who graduated in 1976, to whom questionnaires were sent every 5 years).

Common Rule: A 1981 rule of ethics in the United States regarding biomedical and behavioral research involving human subjects.

comparison group: Commonly known as the *control group*; a group not receiving a treatment, reward, or intervention.

concept: A term that abstractly describes and names an object or phenomenon, thus providing it with a separate identity or meaning.

conceptual framework: A set of highly abstract, related constructs that broadly explains phenomena of interest, expresses assumptions, and reflects a philosophical stance.

conclusions: Opinion or interpretation of the results or meaning of a study.

confidence interval: The range of values within which a population parameter is estimated to lie.

confidence level: The estimated probability that a population parameter lies within a given confidence interval.

confidentiality: Management of data in research so subjects' identities are not linked with their responses. This differs from *anonymity*, in which the subjects' identities are not known.

confirmability: The ability of researchers to accomplish or reproduce the results of a qualitative study.

confounding variable: An uncontrolled variable that may compete with a manipulated variable for interpretive priority. Makes a clear interpretation of the results of a study difficult or impossible.

consent form: A form used to document a subject's agreement to participate in a study.

construct (pronounced with emphasis on first syllable): An image, idea, or theory that has some general meaning that is not directly observable.

construct validity: The degree to which a measure relates to other variables as expected within a system of theoretical relationships. In other words, construct validity is based on the logical relationship among variables (e.g., patients who report that they are satisfied with their physician assistant are more likely to comply with treatment).

content analysis: Qualitative analysis technique to classify words in a text into a few categories chosen because of their theoretical importance.

content validity: The extent to which the method of measurement includes all of the major elements relevant to the construct being measured.

control: Rules imposed by the researcher to decrease the possibility of error and increase the probability that the study's findings are an accurate reflection of reality.

control group: A group of subjects to whom *no* experimental stimulus, treatment, or intervention is administered and who should resemble the experimental group in all other respects (also known as *comparison group*).

convenience sampling: Simply entering available subjects into the study until the desired sample size is reached (also known as *accidental sampling*).

copyeditor: The person who makes corrections on a manuscript to achieve consistency in style, word usage, and spelling, following the appropriate publication guidelines.

correlation: A consistent relationship between two variables such that one variable can be predicted from knowledge of the other. With a *positive correlation*, both variables increase together, that is, a positive value increase. Positive does not mean good, beneficial, advantageous, or better. With a *negative correlation*, one increases when the other decreases or one variable is high and the other is low. Negative does not mean bad, adverse, worse, or least.

correlation analysis: Statistical procedure conducted to determine the direction (positive or negative) and magnitude (strength) of the relationship between two variables.

correlation coefficient (*r*): A statistic that shows the degree of relationship between two or more variables.

cost–benefit analysis: Economic technique that examines costs and benefits of alternative ways of using resources to determine which way produces the greatest net benefit, assessed in monetary terms.

covariance: The measure of effect by two or more variables.

credibility: A term used in qualitative research meaning that the study is performed in an appropriate and rigorous manner.

D

data: The reports of observations of variables.

data collection: Precise, systematic gathering of information relevant to the research purpose or the specific objectives, questions, or hypotheses of a study.

data entry: The process of entering data (usually in coded form) into an input medium.

decontextualized: Consider something in isolation from its context.

degrees of freedom (df): Equal to the sum of the two sample sizes, minus the value 2 ($n_1 + n_2 - 2$). The different rows in the *t* table, each showing a different value of df, accommodate the changes in the sampling distribution of *t* because the sizes of samples may vary.

demographic differences: Characteristics or attributes of the subjects that are collected to describe the sample.

dependability: In qualitative research, the confidence in the data collection methods (analogous to reliability in traditional research terminology).

dependent variable: A phenomenon that is affected by the researcher's manipulation of an independent variable.

description: The precise measurement and reporting of the characteristics of a population or phenomenon under study.

descriptive method: A research plan undertaken to define the characteristics and/or relationships of variables, based on systematic observation of these variables.

descriptive statistics: Calculated values that represent certain overall characteristics of a body of data.

design: Blueprint for conducting a study that maximizes control over factors that could interfere with the validity of the findings.

diary: A written record of a subject's observations and feelings, collected by the researcher for analysis.

distribution: A collection of measurements usually viewed in terms of the frequency with which observations are assigned to each category or point on a measurement scale.

E

editor: The person in charge of a research publication who decides which articles are to be published, manages the overall production of the publication, and heads the editorial staff.

effect size: A statistical expression of the magnitude of the difference between two variables, or the magnitude of the difference between two groups, with regard to some attribute of interest.

emic: Relating to or denoting an approach to the study or description of a particular language or culture in terms of its internal elements and their functioning rather than in terms of any existing external scheme.

ethical principles: Principles of respect for persons, beneficence, and justice relevant to the conduct of research.

ethics: The values or guidelines that should govern decisions in research or medicine. The social obligation the researcher has to his or her subjects.

etic: Relating to or denoting an approach to the study or description of a particular language or culture that is general, nonstructural, and objective in its perspective.

eugenics: The science of improving a human population by controlled breeding to increase the occurrence of desirable heritable characteristics. Developed largely by Francis Galton as a method of improving the human race, it fell into disfavor only after the perversion of its doctrines by the Nazis.

exclusion criteria: Sampling requirements identified by the researcher that eliminate or exclude an element or subject from being in a sample.

experimental group: The subjects who are exposed to an experimental treatment or intervention.

experimental method: A research plan undertaken to test relationships among variables based on systematic observation of variables that are manipulated by the researcher.

experimental research: Any research conducted with a scientific approach, where a set of variables are kept constant while the other set of variables are being measured as the subject of experiment. Experimental research is one of the founding quantitative research methods.

external validity: The degree to which the results of a study generalize to the population. The process of testing the validity of a measure, such as an index or scale, which is conducted by examining its relationship to other, presumed indicators of the same variable.

F

***F*:** Designation letter for the value derived from an *F* test.

forced response: Not offering the opportunity for neutral response. If a respondent is truly neutral, he or she may not respond.

***F* ratio:** A statistical value used in analysis of variance and other statistical methods.

***F* table:** A table of values that represent the percentage points of the *F* distribution.

***F*-test:** A test for comparing two or more means: The ratio of variance between groups divided by the variance within groups (error). As the number of observations in each sample (n) increases, the critical value of *F* increases; smaller differences between the variances of the samples will become significant because variations tend to level out as the proportion of the population sampled increases.

findings: The translated and interpreted results of a study.

focus group interview: An interview in which the respondents are a group of individuals with some trait in common who are assembled to answer questions on a given topic.

frequency distribution: A description of the number of times the various attributes of a variable are observed in a sample.

G

generalizability: The quality of a research finding that justifies the inference that it represents something more than the specific observations on which it was based. Sometimes, this involves the generalization of findings from a sample to a population.

H

Hawthorne effect: A term coined in reference to a series of productivity studies at the Hawthorne plant of the Western Electric Company (Chicago). The researchers discovered that their presence affected the behavior of the workers being studied. The term now refers to any impact of research on the subject of study.

heterogeneous: Having a wide variety of characteristics; the use of heterogeneous subjects reduces the risk of bias in studies not using random sampling.

hypothesis: A provisional theory set forth to explain some class of phenomena, either accepted as a guide to future investigation (working hypothesis) or assumed for the sake of argument and testing. A statement to be tested in a study. An expectation about the nature of things derived from a theory.

hypothesis testing: The determination of whether the expectations that a hypothesis represents are, indeed, found to exist in the real world.

I

inclusion criteria: Sampling requirements identified by the researcher who must be present for the element or subject to be included in the sample.

independent variable: A phenomenon that is manipulated by the researcher and is predicted to have an effect on another phenomenon. A variable whose values are *not* problematic in an analysis but are taken simply as given. An *independent variable* is presumed to cause or determine a *dependent variable.*

indicator: A thing or person that indicates and, therefore, can serve as a proxy for a concept.

induction: The logical model in which general principles are developed from specific observations.

inferential statistics: Statistical methods that make it possible to draw tentative conclusions about a population based on observations of a sample selected from that population and furthermore make a probability statement about those conclusions to aid in their evaluation; inferential methods include sampling theory, hypothesis testing, and parameter estimation.

informed consent: The process used to inform subjects of the risks, benefits, and goals of research studies.

institutional review: A process of examining study proposals for ethical concerns by a committee representing an institution.

internal validity: The extent to which the individual items comprising a composite measure are correlated with the measure itself.

interpretation: The action of explaining the meaning of something.

interrater reliability: The degree of consistency between two raters who are independently assigning ratings to a variable or attribute being investigated.

interval scale: Interval measure; the assignment of numbers to identify ordered relations of some characteristic. The interval scale is arbitrarily assigned and at equal intervals but has no zero point.

interview: Structured or unstructured verbal communication between a researcher and a subject, during which information is obtained for a study.

introspection: The examination or observation of one's own mental and emotional processes.

K

kurtosis: The sharpness of the peak of a frequency-distribution curve.

L

level of significance: In the context of tests of statistical significance, the degree of likelihood that an observed, empirical relationship could be attributable to sampling error. For example, a relationship is significant at the .05 level if the likelihood of its being only a function of sampling error is no greater than 5 out of 100.

Likert scale: A type of composite measurement in survey questionnaires. Likert items use response categories such as strongly agree, agree, disagree, and strongly disagree. Pronounced Lick-ert.

literature review: A review of prior relevant literature that serves as the basis or beginning point for a research endeavor.

longitudinal study: A study design involving the collection of data at different points in time.

M

Mann-Whitney *U* test: A nonparametric hypothesis-testing procedure used to decide whether two given independent samples could have arisen by chance from identically distributed populations; a test for comparing two populations based on independent random samples from each.

MANOVA (multivariate analysis of variance): A general term for analysis using two or more independent variables.

matrix: A two-dimensional organization; each dimension is composed of several positions or alternatives. Any particular "score" is a combination of the two dimensions.

mean (M): The sum of the scores in a distribution of a population or collection of things divided by the number of scores. In common usage, the average.

measurement: A scheme for the assignment of numbers or symbols to specify different characteristics of a variable. Characteristics include validity, accuracy, precision, and reliability.

measures of central tendency: Statistical procedures (mean, median, mode) for determining the center of a distribution of scores or a typical value.

median: The midpoint or midscore in a distribution. The middle number in a sequence of numbers.

member checking: A technique used in qualitative research to establish credibility. Study participants are asked to verify the accuracy of data collection and/or interpretation.

MeSH (Medical Subject Headings): A comprehensive controlled vocabulary for the purpose of indexing journal articles and books in the life sciences; it serves as a thesaurus that facilitates searching.

meta-analysis: The statistical integration of the results of a number of independent studies.

methodology: A system of methods used in a particular area of study or activity.

mode: The most frequent score in a distribution.

mortality: Subjects who are lost to a study or drop out from the study or a group. It does not necessarily mean the death of the subject.

N

narrative review: When the reviewer reads and thinks about a collection of relevant studies and then writes a narrative account of whether the hypothesis under consideration seems to be supported by the evidence.

natural setting: Field settings or uncontrolled, real-life situations examined in research.

needs assessment: Questions concerned with discovering the nature and extent of a particular social problem to determine the most appropriate type of response.

negative case analysis: A technique used by qualitative researchers to enhance credibility by seeking out aberrant examples or data that do not initially fit.

nominal scale: Designation of subclasses by assigning numbers or symbols that represent unique characteristics. It is the weakest level of measurement because it denotes the least information about observations (e.g., eye color: Blue = 1; Brown = 2).

nonparametric statistics: Tests that do not directly incorporate estimates pertaining to population characteristics. Examples are chi-squared, log-linear models, and Wilcoxon matched-pairs signed ranks tests.

null hypothesis: A statement that statistical differences or relationships have occurred for no reason other than the laws of chance operating in an unrestricted manner. The null hypothesis is sometimes stated instead of or in addition to the hypothesis. It is a form of the hypothesis stated in a negative manner.

Nuremberg Code: Nazi doctors were convicted of crimes committed during human experiments on concentration camp victims. The code attempted to give clear rules about what was legal and what was not when conducting human experiments.

O

objectivity: A characteristic of the scientific method; the condition in which to the greatest extent possible the researcher's values and biases do not interfere with the study of the problem.

one-tailed test: A directional hypothesis test that incorporates a rejection region in only one tail of the probability curve used for a given statistic. In setting up a directional hypothesis, the researcher must be very confident beforehand that there is no reason to expect differences in an opposite direction. Used only when there is very good reason to make a directional prediction.

ordinal scale: The assignment of numbers or symbols to identify ordered relations of some characteristic, the order having unspecified intervals. Ordinal scales do not represent the magnitude of differences, only order or ranking.

outcomes research: Method developed to examine the end results of patient care; the strategies used are a departure from traditional scientific endeavors and incorporate evaluation research, epidemiology, and economic theory perspectives.

outliers: Extreme scores, which can change the mean and violate homogeneity of variance.

P

***P* value:** The probability value level used to accept or reject a study value as significant or nonsignificant. For instance, $p < .05$. Thus, if researchers report that a difference was "significant at the $p < .05$ level," they are saying that the probability of the outcome was less than 5 percent due to chance.

paired sample: Two matched groups that are studied before and after the same intervention. Also used to describe a single group that undergoes the same measurement before and after some intervention. Also known as a matched sample.

paradigm: A way of looking at a natural phenomenon that encompasses a set of philosophical assumptions and that guides the approach to inquiry.

parameter: A characteristic of a population or sample.

parametric test: Statistical test that requires interval data and the assumption of a normally distributed population.

participant observation: A data collection method used by some qualitative researchers who embed themselves in the environment and activities of the study's participants. See *field research*.

Pearson's *r* or Pearson's product-moment correlation coefficient: A parametric test used to determine the relationship between variables.

peer debriefing: A technique used in qualitative research to enhance credibility. Peer debriefers are knowledgeable colleagues who help the investigator deal with emotions, test working hypotheses, and resolve ethical dilemmas.

persistent observation: A technique used by qualitative researchers to enhance credibility, exemplified by researchers who strive for deeper meaning over time or from probing.

phenomenon: Any object or event, the characteristics of which can be observed. Plural is *phenomena*.

PICO (Population, Intervention, Comparison, and Outcome): Used to develop literature search strategies. The **PICO** acronym stands for. P – patient, problem or population. I – intervention. C – comparison, control or comparator. O – outcome.

pilot study: A smaller version of a proposed study conducted to develop or refine the methodology, such as the treatment, instrument, or data collection process.

population: The total number of members (or persons) in a defined group.

population distribution: The frequency with which observations in a population would be assigned or expected.

power: The probability that a statistical test will detect a significant difference that exists.

power analysis: Analysis used to determine the risk of a type II error, so the study can be modified to decrease the risk if necessary.

precision: The exactness of the measure used in an observation or description of an attribute.

prediction: The ability to estimate the probability of a specific outcome in a given situation.

predictive validity: The degree to which an instrument can predict some criterion observed at a future time.

principal investigator: In a research grant, the individual who has primary responsibility for administering the grant and interacting with the funding agency.

proposal: Written plan identifying the major elements of a research study, such as the problem, purpose, and framework, and outlining the methods to conduct the study. A formal way to communicate ideas about a proposed study to receive approval to conduct the study and to seek funding.

prospective study: Relating to or being a study (as of the incidence of disease) that starts with the present condition of a population of individuals and follows them into the future.

Q

qualitative analysis: The non-numerical examination and interpretation of observations for the purpose of describing and explaining the phenomena that those observations reflect.

quantitative research: The use of applied mathematics to assist in the research process.

quasi-experimental designs: Research designs that have the characteristics of experimental design but lack randomization.

R

***r^2*:** Coefficient of determination. Indicates the percent variance of y accounted for by x_1 and x_2 in combination.

random sample: A collection of phenomena selected such that each phenomenon in the population has an equal chance of being selected.

range: The highest score in a distribution minus the lowest score.

ratio scale: The assignment of numbers to identify ordered relations of some characteristic, the order having been arbitrarily assigned and at equal intervals, but with an absolute zero point. The ratio scale specifies values and differences that are applicable to arithmetic operations and to statements about phenomena. Age is a ratio measure (scale).

references: The specific items or units used as information resources for a study or written report. References can be texts, journal articles, individuals, and so on. They are generally noted in the body of a report and listed in the bibliography.

referential adequacy: A technique used by qualitative researchers in which they collect a separate set of data for comparison with the initial data.

regulated research: A FDA-regulated test article or is otherwise subject to FDA regulation and determined to be Human Subject Research because it meets the definition of human research subject regulated by the FDA that is subject to IRB review.

relative risk (RR): A ratio that represents the probability of developing an outcome within a specific period when a risk factor is present, divided by the probability of developing the outcome in the same period if the risk factor is not present.

reliability: The external and internal consistency of a measurement. In the abstract, whether a particular technique, applied repeatedly to the same object, would yield the same result each time.

replication: The act or process of replicating, especially for experimental purposes.

representativeness: That quality of a sample having the same distribution of characteristics as the population from which it was selected. By implication, descriptions and explanations derived from an analysis of the sample may be assumed to *represent* similar ones in the population. Representativeness is enhanced by probability sampling and provides for generalizability and the use of inferential statistics.

research: Diligent and systematic inquiry or investigation into a subject in order to discover or revise facts, theories, or applications.

research design: The plan, protocol, format, and parameters of a research project.

research hypothesis: A statement expressing differences or relationships among phenomena, the acceptance or nonacceptance of which implies the existence of a null hypothesis that is susceptible to a probability estimate.

research methods: The significance methods used in systematic inquiry into a subject in order to discover or revise facts, theories, and the like.

response rate: The number of persons participating in a survey divided by the number selected in the sample, in the form of a percentage; the percentage of questionnaires sent out that is returned.

retrospective study: Relating to or being a study (as of a disease) that starts with the present condition of a population of individuals and collects data about their past history to explain their present condition.

risk: A situation involving exposure to danger.

robust: In terms of a statistic, remaining useful even when its assumptions are violated.

S

sample: A collection of phenomena selected to represent some well-defined population.

sampling distribution: The frequencies with which particular values of a statistic would be expected when sampling randomly from a given population.

scale: A specific scheme for assigning numbers or symbols to designate characteristics of a variable. Nominal, ordinal, interval, and ratio are examples of scales. Scales can be single-item or multiple-item measures.

scatterplot: A two-dimensional dot plot that places data in an x and y grid.

significance: The level of calculated probability that is sufficiently low to serve as grounds for rejection of the null hypothesis.

skewed: Unusual or odd distributions.

specification: Explanatory and clarifying comments about the handling of difficult or confusing situations that may occur with regard to specific questions in a questionnaire.

standard deviation (SD): The square root of the mean of the squared deviation scores about the mean of a distribution; more simply, the square root of the variance. SD gives a basis for estimating the probability of how frequently certain scores can be expected to occur in a sample.

standard error of the mean: The standard deviation of a distribution of sample means; describes the likely deviations of sample means about the population mean.

statistic: A characteristic of a sample. Statistics are mathematical models that provide a framework for reasoning so that generalized statements can be made about the data. Types include descriptive and sampling statistics.

statistical analysis: A component of data analytics. Statistical analysis involves collecting and scrutinizing every data sample in a set of items from which samples can be drawn. A sample is a representative selection drawn from a total population.

statistical inference: The process of estimating parameters from statistics.

statistical test: A test that addresses the question, "Could the observed relationship between *x* and *y* have occurred by chance?" Statistical tests state the relationship between variables by some specified degree.

systematic review: A form of analysis that medical researchers carry out to synthesize all of the available evidence on a particular question, such as how effective a drug is. It pools numerical analyses from studies of similar design. A meta-analysis can also form part of a further systematic review.

T

***t* table:** A statistical table of percentage points of the *t* distribution. Used with statistical analyses that produce a *t* value.

***t*-test (student's *t*-test):** Test of the difference between two population means, based on the observed difference between two sample means and their distribution.

thick description: A technique used by qualitative researchers that reveals the lived experience of participants in a way that evokes a human response and meaningful interpretation.

treatment modality: The method used to treat a patient for a particular condition.

two-tailed test: A nondirectional hypothesis test that incorporates rejection regions in both tails of the probability curve used for a given statistic. Also known as nondirectionality tests.

type I error: Rejecting a null hypothesis when it should have been retained.

type II error: Retaining a null hypothesis when it should have been rejected.

U

unitization: The breaking down of qualitative data into separate pieces of meaning that can stand alone.

V

validity: The degree to which a scale is in fact consistently measuring the variable that it was designed to measure.

variable: An observable characteristic of an object or event that can be described according to some well-defined classification or measurement scheme.

variance: The mean of the squared deviation scores about the mean of a distribution.

W

Wilcoxon test: A nonparametric test for use with related samples.

Wilks's lambda: A commonly used test for group mean equality in multivariate tests.

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